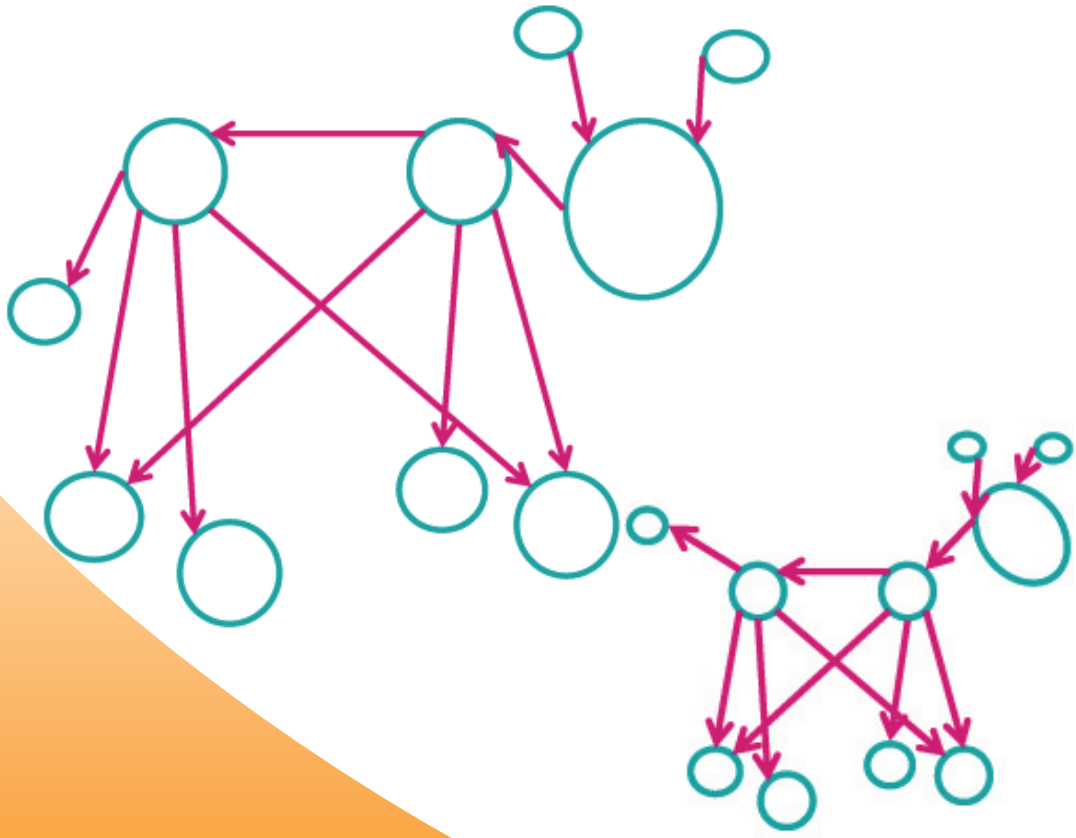
Evira Research Reports 4/2008

Pirkko Tuominen

Developing risk-based food safety management



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DEVELOPING RISK-BASED FOOD SAFETY MANAGEMENT

Pirkko Tuominen

ACADEMIC DISSERTATION

To be presented with the permission of Faculty of Veterinary Medicine,
University of Helsinki,
for public examination in Auditorium Arppeanum
Snellmaninkatu 3, Helsinki on 9th January 2009, at 12 o'clock noon
HELSINKI 2009

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ISSN 1796-4660, ISBN 978-952-225-013-1 (print)
ISSN 1797-2981, ISBN 978-952-225-014-8 (pdf)
Helsinki University Print 2008

AKNOWLEDGEMENTS

This study was carried out in the Risk Assessment Unit, Finnish Food Safety Authority Evira (and its predecessor the National and Food Research Institute, EELA) and at the Department of Food and Environmental Hygiene, Faculty of Veterinary Medicine, University of Helsinki. The work was financially supported by the Finnish Food Safety Authority Evira, the Finnish Funding Agency for Technology and Innovation, the Finnish Veterinary Foundation and the Walter Ehrström Foundation. Also, the financial support from the University of Helsinki is gratefully acknowledged.

I thank the heads of the former and present institutes, Director General Jaana Husu-Kallio, Director Tuula Honkanen-Buzalski, and the present Head of the Risk Assessment Unit Kirsti Savela, for positive attitude and working facilities during the past years. I am very grateful to my supervising professor, Professor Hannu Korkeala for his encouragement and practical advice during this work.

I'm deeply indebted to my supervisor, Director Riitta Maijala, former head of our unit, for her dynamic contribution, tireless response and for sharing thoughts related to the fascinating world of risk analysis. My special thanks go to Docent Jukka Ranta, co-author and research fellow, my enthusiastic 'tutor' and assiduous critic, who provided the Bayesian models for the works I-III. Without him, the most honoured Reverend Bayes could be a complete stranger to me. I also want to express my warm thanks to my co-authors Laura Raaska, Kaarina Aarnisalo and Sebastian Hielm for their efforts and inspiring cooperation during all these years.

My sincere thanks are due to the official reviewers, DVM Ph.D. Moez Sanaa, and DVM Ph.D. Birgit Nørrung, for their incentive comments. Ph.D. Roy Siddall from the Language Centre of Helsinki University is thanked for the superior language revision. Vicky Karhu is thanked for her generous help along the process.

I express my gratitude to my colleagues and friends, and numerous collaborators at Evira and elsewhere, especially veterinary counsellor Terhi Laaksonen is warmly thanked. Risk assessment always benefits from multifaceted and interdisciplinary cooperation. Countless debates and discussions that have taken place in our unit during the years have helped me grow as a researcher as well as a person. Without you, this thesis would never have been the same.

I also wish to thank my parents, my relatives and my friends for their love and support. Last but not least, I want to thank my family. Thank you Eero, Annika, Mikael and Pekka for the journey this far.

Helsinki, December 2008

Pirkko

TERMINOLOGY AND ABBREVIATION

Appropriate level of protection, ALOP

The level of protection deemed appropriate by the member (country) establishing a sanitary or phytosanitary measure to protect human, animal and plant life or health within its territory (WTO 1995)

Dose-response assessment

The determination of the relationship between the magnitude of exposure (dose) to a chemical, biological or physical agent and the severity and/or frequency of associated adverse health effects (response) (Codex Alimentarius 1999)

Exposure assessment

The qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant (Codex Alimentarius 1999)

Food

Any substance, whether processed, semi-processed or raw which is intended for human consumption, including drinks, chewing gum and any substance which has been used in the manufacture, preparation or treatment of "food" but excluding cosmetics, tobacco and substances used only as drugs. (Codex Alimentarius 1995)

Food hygiene

Conditions and measures necessary for the production, processing, storage and distribution of food designed to ensure a safe, sound, wholesome product fit for human consumption (FAO/WHO 2007)

Food safety

Assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use (Codex Alimentarius 1969)

Food safety metrics

Intermediate metrics such as FSO, PO and MC, converting ALOP to measurable targets for the food industry (FAO/WHO 2006)

Food safety objective, FSO

The maximum frequency an/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (Codex Alimentarius 2004)

Hazard

A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect (Codex Alimentarius 1999)

Hazard analysis and critical control points, HACCP

A system which identifies, evaluates, and controls hazards which are significant for food safety (Codex Alimentarius 1969, 2003)

Hazard characterization

The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents which may be present in food. For chemical agents, a dose-response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable. (FAO/WHO 2007)

Hazard identification

The identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods. (FAO/WHO 2007)

In-house control

Control system followed by a food operator including voluntary food safety, quality assurance and obligatory OCP.

Interested parties

Risk assessors, risk managers, consumers, industry, the academic community and, as appropriate, other relevant parties and their representative organizations. (FAO/WHO 2007)

Markov chain Monte Carlo sampling, MCMC

Method that generates random numbers from a defined distribution with Markov chain sampling techniques.

Microbiological criteria, MC

A criterion defining the acceptability of a product or a food lot, based on the absence or presence, or number of microorganisms including parasites, and/or quantity of their toxins/metabolites, per unit(s) of mass, volume, area or lot. (Codex Alimentarius 1997)

Microbiological risk assessment, MRA

Risk assessment of microbiological hazards in food. (Codex Alimentarius/GL 1999)

Microbiological risk management, MRM

Microbiological risk management of microbiological hazards in food. (Codex Alimentarius/GL 2007)

Own-checking programme, OCP

An obligatory food safety management system regulated for food operators. It consists of a supporting system (hygiene conditions, measurements, products and their control), HACCP system, and hygiene and OCP training of the personnel. The food companies are obliged to present the programme in a written form, to execute it, and to keep a record of the measures taken. (Food Act 23/2006)

Performance criterion, PC

The effect in frequency and/or concentration of a hazard in a food that must be achieved by the application of one or more control measures to provide or contribute to a PO or an FSO. (Codex Alimentarius 2004)

Performance objective, PO

The maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption that provides, or contributes to, an FSO or ALOP, as appropriate. (Codex Alimentarius 2004)

Precautionary principle

An option open to risk managers when decisions have to be made to protect health but scientific information concerning the risk is inconclusive or incomplete in some way. (EC 2002)

Process criterion

The physical process control parameters (e.g. time, temperature) at a specified step that can be applied to achieve a performance objective or performance criterion. (Codex Alimentarius /RCP2005)

Risk

A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food. (Codex Alimentarius 1999)

Risk analysis

A process consisting of three components: risk assessment, risk management and risk communication. (Codex Alimentarius 1999)

Risk assessment, RA

A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization. (Codex Alimentarius 1999)

Risk-based

Containing any performance objective, performance criterion or process criterion developed according to risk analysis principles (interim definition). (Codex Alimentarius 2005b)

Risk-based food safety management

Food safety management based on risk assessment in order to achieve an appropriate level of protection (ALOP).

Risk characterization

The process of determining the qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known of potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment. (Codex Alimentarius 1999)

Risk communication, RC

An interactive process of exchange of information and opinion on risk among risk assessors, risk managers, and other interested parties. (Codex Alimentarius 1999)

Risk estimate

Output of risk characterization. (Codex Alimentarius 1999)

Risk management, RM

The process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures. (Codex Alimentarius 1999)

Risk manager

A national or international governmental organisation with responsibility for MRM. (Codex Alimentarius 2007a).

Risk profile

A description of a food safety problem and its context so as to guide further risk management.

Qualitative risk assessment

A risk assessment based on data which, while forming an inadequate basis for numerical risk estimations, nonetheless, when conditioned by prior expert knowledge and identification of attendant uncertainties permits risk ranking or separation into descriptive categories of risk. (Codex Alimentarius 1999)

Quantitative risk assessment, QRMA

A risk assessment that provides numerical expressions of risk and indication of the attendant uncertainties. (Codex Alimentarius 1999)

SPS Agreement, Agreement on Sanitary and Phytosanitary Measures

Entered into force in 1995 with the establishment of the WTO. Concerns the application of food safety and animal and plant health regulation. (WTO 1995)

ABSTRACT

The drive for risk-based food safety management, systems and control has spread world-wide in recent decades. Since the term is still internationally undefined, its use and implementation vary, producing different realizations. In this Ph.D. thesis, microbiological risk assessment (MRA) was investigated as a basis for risk-based food safety management, which was defined as 'food safety management based on risk assessment in order to achieve an appropriate level of protection (ALOP)'. Governments are responsible for commissioning MRAs and also for setting food safety targets up to a certain point, but the practical management measures that need to be in place in order to achieve the targets are to be addressed by the operators. On the plant level, food safety is usually managed through regulation, quality assurance systems and a hazard analysis and critical control point (HACCP) programme with its prerequisites. In Finland, food safety management on the food plant level is implemented through an HACCP-like regulated system termed an own-checking (OC) programme.

A quantitative microbiological risk assessment (QMRA) was conducted on salmonella in the beef production chain according to the official standards of the Codex Alimentarius Commission (Codex Alimentarius), and utilized in determining the food safety metrics for beef production. The Finnish Salmonella Control Programme (FSCP) and the main official interventions due to it were examined in the light of risk-based food safety management. The targets set for beef processing plants by the government were converted into quantitative limits, and the results of salmonella monitoring included in the FSCP were examined by the QMRA. The goal of the FSCP was declared in 1994 to 'maintain the present salmonella situation', which was considered to refer to the salmonella incidence in humans at that time, and also the *de facto* ALOP.

The requirement for a maximum salmonella prevalence of 1% at defined stages of the beef production chain was embodied in the FSCP. This statement was considered to convey performance objectives (PO) for the aforementioned stages. According to the QMRA, the *de facto* ALOP was achieved in the referred year 1999, and even the true prevalence levels in the FSCP were estimated to be clearly under the set PO limits with 95% credibility. However, the PO limits were set too high for the *de facto* ALOP to be maintained in practice. If the salmonella prevalence reached the PO limit of 1% or values near it, the public health risk would increase and overrun the *de facto* ALOP. The QMRA produced in this work has for the first time provided the possibility to quantitatively asses the relationships between targets set in the FSCP and their impact on public health. At present, imports of beef and beef-derived foods may impose on Finnish consumers a significantly greater exposure than domestic products. If their salmonella prevalence or their share of the foods consumed in Finland increase, the number of human cases could rapidly rise.

The models for the QMRA were mainly Bayesian hierarchical models using Markov chain Monte Carlo (MCMC) techniques, which was found to be a flexible and appropriate method for this type of complex modelling. The resulting distributions were also regarded as an advantage compared to the results from models developed with the deterministic approach, because the presentation of results included the extent of the uncertainty, and also in this manner better illustrated the actual operational environment.

Based on an inquiry, the personnel in food processing plants had a positive attitude towards food safety management systems, but the knowledge, training and involvement of those employees directly operating on the site with these systems were discovered to be deficient. Therefore, a generic semi-quantitative hygiene risk assessment model, Hygram®, was developed for small and medium-sized food enterprises to offer assistance in understanding, training, and, first of all, detecting the critical steps of the processes, and thereby to contribute to the development of their own-checking systems towards risk-based food safety management. Hygram® was not considered a risk-based tool as such, but whenever the critical limits of the process have been defined as equal to a risk assessment, Hygram® can be used as a risk-based management tool. It can also serve as a tool for systematic hazard analysis and CCP detection when establishing a food safety management system.

To conclude, the development of risk-based food safety management is a process in which risk assessment is an essential tool. Scientific, technical, psychological and resource-bound barriers need to be overcome in order to put risk-based management systems into practice. This study showed that QMRA can be valuable in national risk management decision making, although few QMRAs are currently available. Appropriate tools for practical risk management decision making on the industrial level, such as Hygram®, need to be further developed.

CONTENTS

LIST OF ORIGINAL PUBLICATIONS

I Ranta J, Tuominen P and R Maijala, 2005 Estimation of true salmonella prevalence jointly in cattle herd and animal populations using Bayesian hierarchical modeling. Risk Analysis 25: 23-37.

II Tuominen P, Ranta J and R Maijala, 2006. Salmonella risk in imported fresh beef, beef preparations and beef products. Journal of Food Protection 69: 1814-1822.

III Tuominen P, Ranta J and R Maijala, 2007. Studying the effects of POs and MCs on the salmonella ALOP with a quantitative risk assessment model for beef production. International Journal of Food Microbiology. 118: 35-51.

IV Hielm S, Tuominen P, Aarnisalo K, Raaska L and R Maijala, 2005. Attitudes towards own-checking and HACCP plans among Finnish food safety industry employees. Food Control 17: 402-407.

V Tuominen P, Hielm S, Aarnisalo K, Raaska L and R Maijala, 2003. Trapping the food safety performance of a small or medium-sized food company using a risk-based model. The HYGRAM® system. Food Control 14: 573-578.

The publications are referred to in the text by their Roman numerals.

1 INTRODUCTION

Foodborne diseases are a global threat as a result of the increase in international travel and trade, microbial adaptation and changes in the food production system, as well as human demographics and behaviour (D'Aoust 1994, WHO 2002; Schlundt et al. 2004; Patil et al. 2005). Food and waterborne diarrhoeal diseases are considered as the leading causes of illness and death in less developed counties (Schlundt et al. 2004), causing an estimated 1.9 million deaths annually in the world (Käferstein and Abdussalam 1999). Up to one third of the population in developed countries has been estimated to be affected by microbiological foodborne disease every year. The majority of foodborne pathogens are zoonotic (Käferstein and Abdussalam 1999). It has also been estimated that bacteria are responsible for about 60% of the foodborne illnesses that lead to hospitalization and that they contribute almost two-thirds of the deaths due to foodborne pathogens. Salmonella has been identified one of the main hazards causing foodborne illnesses in the world, both in developing and developed countries.

In the mid-1990s, when scientific-based risk assessment was set as one of the basic principles of the decision making and rules of free trade (WTO 1995), risk assessment also started to develop as a field of science in the food safety area. It was considered as a method with which the current level of health protection (appropriate level of protection, ALOP) in a country could be expressed, and thus a means to be exploited when evaluating trade barriers. As defined in the risk assessment, foodborne risk was also recognised a two-dimensional factor with both the probability and severity having to be taken into account. Since then, management of the risks concerning plant and animal production as well as public health has proceeded towards the scheme of implementing a risk assessment approach.

As food production has changed during recent decades from local, short and simple food chains to international, branched and refined supply systems, the importance of microbiological risk assessment (MRA) has been recognized. As a consequence, MRA has been considered an essential basis for the management of foodborne hazards, both on governmental and local levels. Authorities and operators have been urged to implement risk-based food safety management and control by national and international risk managers (WTO 1995, EC 2000b, Regulation (EC) No 852/2004, Finnish Food Agency 2000, Nordic Council of Ministers 2007). This, in turn, has initiated research into how to utilise MRA results in control and follow-up in the guidance of the Codex Alimentarius Commission (Codex Alimentarius), which was given the mandate with an international agreement (Agreement on Sanitary and Phytosanitary Measures or SPS Agreement) (WTO 1995). Definitions for risk-based food safety targets, i.e. food safety objectives (FSO), performance objectives (PO) and performance criteria (PC), have been introduced (Codex

Alimentarius 2004) in order to convert the ALOP into risk management metrics or targets for food safety systems and control measures with the stringency required to achieve the goal.

Risk analysis with its three interconnected components, risk assessment, risk management and risk communication, has also been considered fundamental when laying down food safety management measures in the European Union (EU) (EC 2000b, EC 2002). According to Regulation (EC) No 178/2002, which expresses the general principles and requirements on which the EU is basing its food safety, other relevant factors, including societal, economic, traditional, ethical and environmental elements, also have to be taken into account when making risk management decisions (EC 2002). The precautionary principle is to be followed in order to set provisional risk management measures in specific circumstances where the possibility of harmful effects on health is identified but scientific uncertainty persists.

No ultimate definition for the term 'risk-based' is provided by the Codex Alimentarius, and it has often been used to refer to anything that is considered risk-related. The Codex Committee on Meat Hygiene defined it in the interim as an attribute describing risk management measures developed according to risk analysis principles (Codex Alimentarius 2005b). A joint FAO/WHO expert meeting regarded risk-based management actions as those achieving the level of health protection that can be explained and validated in terms of risk to human health (Codex Alimentarius 2006). In the animal health sector it has been proposed that a 'risk-based surveillance system' should be defined as one applying risk assessment methods in different steps of traditional surveillance design for the early detection and management of diseases or hazards (Stärk et al. 2006).

Since food safety is of global concern and international agreements advocate the protection of consumer health, governments are responsible for food safety within their territories. A government should declare the public health level it is willing and able to defend and then state the consequential measures with which the target(s) would be maintained. Because food safety risk management is implemented in food producing companies, and they are the operators who are responsible for food safety in the first place, it is essential that adjustment towards "risk-based" management becomes materialized in food companies. A proper change can only happen if the principles of risk-based management are communicated and understood. In order to achieve such understanding, tools that weigh the food safety risks, prioritize them, and are capable of defining the acceptable limits and/or allowing their follow-up, are needed at different levels of food management.

Quantitative microbiological risk assessment (QMRA) can be seen as such a tool, because it allows the existing level of a specified risk along the food chain to be estimated. The(se) estimate(s) can then be exploited as a basis for determining risk-based food safety targets with contributing control measures. QMRAs conducted with similar data, methods and assumptions are comparable and prioritization can therefore be carried out according to their results. The intermediate targets should be convertible into the criteria applied by the industry to their food safety management systems, such as a criterion for the efficacy of the control measure, a definition of the critical limit, or an attribute for the end product. The control measures and criteria

contributing to the intermediate target may then be implemented in the OCP of the company (or other food safety management system), and evaluated and followed in a more practical way. Principles and guidelines on how to conduct microbiological risk assessment (Codex Alimentarius 1999) and microbiological risk management (Codex Alimentarius 2007a) are binding the members of the WTO. The principles concerning the application of the whole risk analysis have also been laid down (Codex Alimentarius 2007b).

2 REVIEW OF THE LITERATURE

2.1 Microbiological risk analysis as a basis for risk-based food safety management

Risk-based food safety management has been urged since risk analysis was launched in the international trade area as a gauge in the 1990s (WTO 1995). Since then, both MRA and its potentially achievable applications have been investigated. Among other challenges remains the basic question of how "risk-based" should be defined in the context of food safety.

Despite the lack of a definition, risk-based food safety management has gradually become a demand and a target on all production levels. In the EU it was expressed as a principle in 2001. Unfortunately, the term was never clearly defined. Recently, some approaches have been developed, definitions suggested (Stärk et al. 2006), guidelines drafted (Nordic Council of Ministers 2007), and methods for risk ranking generated (Sumner and Ross 2002, Anonymous 2008) in order to lay down a procedure.

2.1.1 SPS Agreement

The World Trade Organization (WTO) was established in 1995 as a result of the Uruguay Round of Multilateral Trade Negotiations to promote global free trade. The rules for international trade, concerning food safety as well as animal and plant health regulations defined in the Agreement on Sanitary and Phytosanitary Measures (SPS Agreement), entered into force at the same time (WTO 1995). The Agreement applies to all sanitary and phytosanitary measures that may affect international trade. The measures should only to be applied to the extent necessary to protect human, animal or plant life or health, they should be based on scientific principles and should not be maintained without sufficient scientific evidence. The SPS measures should be based on risk assessment standards provided by international organisations. Such organisations are the FAO/WHO Codex Alimentarius, the World Organization for Animal Health (OIE), and the Secretariat of the International Plant Protection Convention of the FAO (IPPC). Governments can add any other international organizations or agreements whose membership is open to all WTO members (WTO 1995).

The main goal of the SPS Agreement is on the one hand to maintain the sovereign right of its member governments to provide the appropriate level of health protection (ALOP), but on the other hand ensure that this does not form unnecessary trade barriers. The SPS measures applied in

different countries should be accepted as equivalent if they provide the same level of health protection. WTO members are urged to found their SPS measures on the analysis and assessment of objective and accurate scientific data to confirm the justification for the protective measures taken. The measures may only be applied to the extent necessary to protect life or health and they are not allowed to discriminate between national and foreign, or among foreign sources (WTO 2007). Systematic, science-based risk assessment is encouraged to increase transparency in setting and evaluating the measures. The SPS measures may be based on either international standards or scientific risk assessments to prove they are justified. The burden of proof is on the complainant to show that the defendant has violated the provision. Thereupon the defendant has to produce evidence of a risk assessment to which the measure bears a rational relationship (WTO 1998).

2.1.2 Risk analysis

The terms 'equivalency' and 'appropriate level of protection' (ALOP) produced in the SPS Agreement needed harmonized concepts to be applicable in practice (de Swarte and Donker, 2005). The SPS Agreement recognized the requirement for a rigorous scientific process for standards and regulations for international food trade (FAO/WHO 1995). The goal was to contribute to protecting consumers and facilitating international trade in a consistent and open manner despite the limited resources of national governments. The concept of risk analysis was exploited, and the Codex Alimentarius was nominated as one of the officially accepted organizations to develop risk analysis for the food sector.

According to the Codex Alimentarius, risk analysis is a process consisting of risk assessment, risk management and risk communication (Fig.1) (Codex Alimentarius 1999). Risk analysis forms the framework for the interactive activities between risk managers, risk assessors, operators and other interested parties. Generally, risk assessment may be considered as a science-based part of risk analysis making risks understandable, whereas risk management is developing and carrying out actions to reduce the risk when necessary (McKone 1996). Risk management needs to take social, economic and political aspects into consideration when risks are evaluated. All communication exchanged between risk managers, risk assessors and other interested parties is termed risk communication.

Functional separation of risk assessment from risk management has been considered an important principle in order to promote scientific risk assessment as the basis for risk management decisions, although the essence of interactive communication is recognized (Codex Alimentarius 2007a). Risk assessment was defined as a scientific evaluation of the known or potential adverse health effects resulting from human exposure to foodborne hazards (Codex Alimentarius 1999). Official bodies were considered responsible for using risk analysis to determine realistic and achievable risk levels for hazards and for basing food safety policy on the results of these analyses.

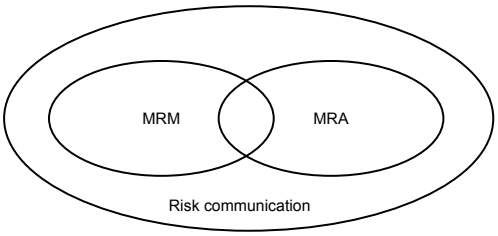

Figure 1. *Microbiological risk management (MRM) and microbiological risk assessment (MRA) are the two bound but separate elements of microbiological risk analysis, where risk communication is the main combining element (Codex Alimentarius 1999).*

Figure 2 illustrates the risk analysis procedure. After a risk manager has decided to conduct a risk assessment, the scope, purpose and policy to be followed are established (Codex Alimentarius 2002). Risk assessment develops models and/or measurements to determine the magnitude of risk, and estimates the parameters and uncertainty concerning this magnitude (McKone 1996). Accordingly, an assessment has to be carried out on the adverse consequences resulting from different options (actions and inactions) available for managing the risk. On the basis of the knowledge achieved, the risk manager can take actions to execute control and risk-reducing measures in order to achieve the public health goals (Lammerding 2006).

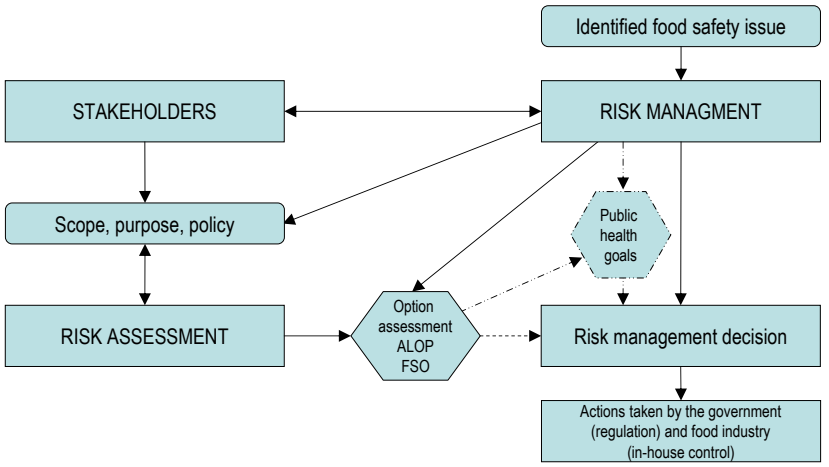

Figure 2. *Decision making according to the microbiological risk analysis process. When a food safety issue has been identified, the risk management is urged to make a decision that may or may not oblige an action. Social, demographic and economic factors (stakeholders) as well as public health goals, if stated, should be taken into account in the decision making. The needs and the problem of the issue guide in setting the scope and the purpose of the risk assessment (risk assessment question). Risk management options, ALOP and FSO may be laid down by the risk management with a contribution from the risk assessment results.*

Risk analysis has been regarded as a framework for organizing data (information) in a systematic and consistent way in order to produce rational and transparent decisions (Käferstein 2000). However, there still are challenging characteristics in biological risk analysis regarding the live nature of the hazards, such as estimates for dose-response and exposure (FAO/WHO 1995, FAO/WHO 2006). Quantitative microbiological targets such as food safety objectives (FSO) and performance objectives (PO) based on MRA have been termed 'food safety metrics' (FAO/WHO 2006). They may be developed for either national or local purposes and used as indicators of the level of control at specific steps in a food safety risk management system.

The commitment of the EU to protect the health and safety of the citizens concerning food was revealed in a White Paper on Food Safety published by the Commission of the European Communities in 2000 (EC 2000b). The Paper proposed recommendations to increase food safety, to improve the traceability of food products, and to regain consumer confidence after several animal disease outbreaks and food contaminant scandals (Dwinger et al. 2007). As a consequence, the general principles and requirements, the establishment of the European Food Safety Authority (EFSA), and food safety procedures were laid down as the general European Regulation (Regulation (EC) No 178/2002) with five legislative parts (Regulation (EC) No 852/2004, Regulation (EC) No 853/2004, Regulation (EC) No 854/2004, Council Directive 2002/99 and Directive 2004/41/EC) at the beginning of the 2000s. Risk analysis with its three components of risk assessment, risk management and risk communication was appointed as the foundation on which EU food safety policy would be based. The farm to table policy was also emphasized as well as transparency in decision making. The task of carrying out risk assessment activities on the European level was given to the EFSA.

2.1.3 Risk management

Risk management has overall responsibility for the protection of consumer health and assurance of fair trade. The term 'risk management' has no textual basis in the SPS Agreement (WTO 2007), but it has been combined with risk assessment as responsible for conducting risk analysis. Based on the SPS Agreement, Codex Alimentarius (2003) considered risk management as "a process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment when available and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and if needed, selecting appropriate prevention and control options." The process can be managed on the national, regional or international level.

ALOP is a key concept in the risk management process (Codex Alimentarius 2006). The primary goal of the management of risks associated with food is to protect public health by controlling such risks as effectively as possible through the selection and implementation of appropriate

measures (FAO/WHO 1997). The continuum of the whole food chain is stressed. Other principles included in the main guidelines promote openness and communication between different interested parties (Table 1) (Codex Alimentarius 2006).

Table 1. *General principles for microbiological risk management (Codex Alimentarius 2006).*

Principle 1	Protection of human health
Principle 2	Consideration of the whole food chain
Principle 3	Structure approach
Principle 4	Transparency, consistency, documentation
Principle 5	Consultation with relevant interested parties
Principle 6	Interaction with risk assessors
Principle 7	Consideration of regional differences (of hazard and management options)
Principle 8	Monitoring, review (and revision)

Food-related microbiological risks are mainly managed by international commitments, governmental regulation and guidelines, and/or operational decisions and agreements made at the production level. Ideally, the government would set an ALOP that is based on risk assessment results and takes demographic aspects, socioeconomics and regional practices into account (Fig. 2). The ALOP would be translated to the food industry as a food safety objective (FSO), a feasible target to be achieved in order to protect consumer health. Either government or industry would set one or several performance objectives (PO) as intermediate checkpoints along the food production chain to guide the production towards the FSO. On the plant level, industry would implement various and diverse options at strategically effective stages.

The responsibility for commissioning a risk assessment belongs to a national or international governmental organization (risk manager) that may adopt it as a tool to help make an informed decision (CX/FH 05/37/6). An identified food safety issue concerning a hazard(s) associated with food(s) starts the MRM process with an initial analysis. The food safety problem and its context are described, potential MRM options identified for the food safety policy context, and the current knowledge related to the problem is processed into a concise form (risk profile). If the issue is a major one needing an objective, systematic evaluation may take place of the relevant scientific knowledge for identifying and selecting MRM options for the risk assessment. It is the task of the risk manager to give the mandate and resources for risk assessment. The risk management question should be clearly defined and risk assessment policy established by the risk manager in collaboration with risk assessors before the commencement of the MRA in order to protect the scientific integrity of the risk assessment. A definition of the risk assessment policy should be laid out before the RA starts, defining the rights and responsibilities of different parties. The responsibility for selecting appropriate MRM options lies with the risk manager, who may utilize

the results of an MRA in the evaluation, comparison and selection of effective and feasible MRM options. Further on, MRA may be exploited when MRM metrics are established for food safety (Fig. 3). They may be referred to as risk-based when developed according to risk analysis principles. (Codex Alimentarius/RCP 58-2005).

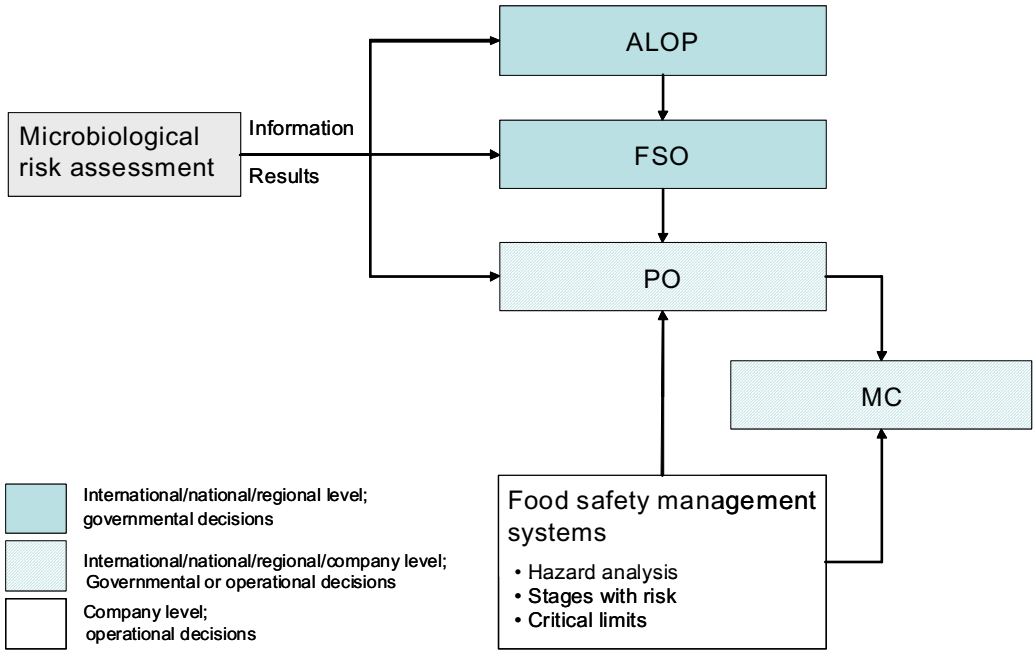

Figure 3. *Responsibilities in risk-based decision making. Governments are unambiguously responsible for stating the appropriate level of protection (ALOP) and food safety objective (FSO), whereas performance objectives and microbiological criteria may be set either by a governmental body or the food operator. The food operator has the main liability for establishing the food safety management system and setting the intermediate goals within it. Results from a risk assessment provide information about the criteria required for both the governmental and industrial decision makers.*

Appropriate level of protection, ALOP and public health goals

Instead of trying to eliminate all hazards from the food supply, ALOP represents the opinion that public health is improved by setting a goal and then determining the frequency and/or level of hazard in food that is compatible with that goal (Zwietering 2005). ALOP was already defined in the SPS Agreement, but interpretation has become diverse. It has been seen either as a target to be

achieved (Codex Alimentarius 2006), a view that was also taken by the European Food Safety Authority (EFSA) (EFSA 2007b), or as the current public health status (FAO/WHO 2006).

If the ALOP is interpreted as an expression of the level of protection achieved in relation to food safety at the current time, it may change over time and can be directly derived from risk assessment results (Fig. 2). Further on, its estimation by means of risk assessment reveals the facts about the existence of equivalency concerning SPS measures. As such, risk management can take actions to execute control measures and interventions, and future public health goals may be set. If, on the other hand, the ALOP is considered as a future objective, its use as a preamble justifying trade restrictions is more complicated. As a governmental target, ALOP would be influenced by the perception of risk, including the degree of outrage associated with a hazard (Walls et al. 2005). However, risks should be consistently regulated when applying the concept of ALOP, because inconsistent ALOPs are suggestive that protectionism rather than health concerns is the dominant motive for the imposition of SPS measures on imported goods (Atik 2004).

If the risk manager has chosen to implement a programme to reduce the burden of illness, e.g. caused by salmonella, it should be done by stating a specific health goal with practical measures, or by evaluating all available risk management options and selecting the ALOP on the basis of the lowest risk level (Stringer 2005).

Some health goals have been set that may be interpreted as ALOP-related objectives. Finland has declared a national goal to maintain its salmonella prevalence on the current level (VNS 2006). In the US, the Food Safety and Inspection Service FSIS of the U.S. Department Agriculture (USDA) has set a goal of 6.8 human salmonella cases / 100,000 persons by 2010 (HHS 2000), i.e. half of that reported in 2005 (14.92/100,000) (CDC 2008). In the UK, the Food Standards Agency expressed its goal as the reduction of all foodborne diseases by 20% by 2006 (FSA 2001), and came close to meeting the target (Bell 2006).

Food safety objective, FSO

To be of use, the ALOP has to be translated into measurable objectives and criteria for the food industry. The concept of the food safety objective (FSO) was developed to link the ALOP to food safety systems used in manufacturing (ICMSF 2002). The FSO should present the frequency and/or concentration of the hazard of concern at the time of consumption (Codex Alimentarius 2004), i.e. at the moment when the hazard level can no longer change (ICMSF 2002), and should thereby connect the derivative risk management measures to the public health impact (Gorris 2005). Originally, the basis for the development of the FSO was the need to explain “the acceptable level of a hazard” to food industry while on the other hand expressing the justification for SPS measures with respect to equivalence (ICMSF 2002). Both the Codex Alimentarius and the ICMSF have developed and interpreted the FSO and its derivatives in order to implement them in the risk management framework.

The FSO has been considered as a concept articulating the joint target of all food chains relevant to a pathogen/commodity combination, and operating as a communication tool for the overall management of the chain (Gorris 2005). Defining the FSO at the point of consumption as a target leaves flexibility for those involved to determine how the earlier points will be achieved (Stringer 2005). When derived from an ALOP, an FSO should act as an integral part of food management, including the results of the MRA, the characteristics and capabilities of the supply chains, and the expressed ambitions of health protection (Gorris 2005). Thereby, food safety management programmes should also become more targeted (van Schothorst 2005), and interventions may be set at the stage where they are most effective (Zwietering 2005). Thus, food safety objectives defined as part of the risk management process should be used to govern Hazard Analysis and Critical Control Point (HACCP) as an outcome definition (Schlundt 1999). Verification and validation are critical in order to assure the compliance of the FSO and its derivatives with the concomitant level of burden of illness (van Schothorst 2005; Walls and Buchanan 2005). If the FSO is not feasible for a product, it has to be revised, a surrogate product has to be used, or the product has to be removed from commerce.

The FSO and other nomenclature for risk management were initially developed separately from risk assessment, which has made their consolidation a challenge. The FSO concept has, however, been concluded to be of limited practical use (FAO/WHO 2006) because of the difficulty in setting an FSO that is able to act in accordance with both intermediate risk-based food safety targets of food production and with the ALOP. The definition has been considered feasible for some ready-to-eat (RTE) products with such intrinsic and extrinsic characters that restrain the growth and spread of pathogens (Stringer 2004; Gorris 2005; Zwietering 2005; Walls and Buchanan 2005), but not realistic for products that are treated after manufacturing prior to consumption (Nauta and Havelaar 2008). The current definition relating to the moment of consumption has not been considered compatible with risk assessment methods and results (Havelaar et. al 2004). The availability of relevant data to estimate the risks at that point may be impossible, because there would be variable and largely unknown effects in food handling and preparation in kitchens. The value of an FSO derived from a QMRA model has also been considered questionable. Alternative definitions have been proposed to describe the FSO at such stages where its estimate could be based on data, such as “A limit to the prevalence and the average concentration of a microbial hazard in food, at an appropriate step in the food chain at or near the point of consumption that provides the appropriate level of protection” (Havelaar et al. 2004). Epidemiological evidence of the public health burden due to a particular pathogen associated with a food product, an MRA, or a microbiological criterion that is already in use have been presented as the basis for the establishment of an FSO by a competent authority (Membré et al. 2007).

Performance objective, PO

In contrast to an FSO, a PO can be utilised at points of the food supply chain where control and verification are possible (FAO/WHO 2006). The FSO is the value that should lead to the development of PO values earlier in the chain when appropriate (Gorris 2005). POs, for one, guide in the development of other risk-based standards that are valid in achieving a specified level of human health protection (Codex Alimentarius 2006). FSOs generally have to be implemented via the establishment of POs, because an FSO has to be directly related to the public health goal (Wallis and Buchanan 2005). On the other hand, an FSO can be regarded the last PO before the dose-response model (Nauta and Havelaar 2008). The main prerequisite for the establishment of a PO and its derivatives is the existence or knowledge of the degree of public health protection the risk managers aim to achieve or maintain. A PO may be established by the government or an individual production plant may establish its own POs. Setting a PO helps to shift the management system from compliance with specific processes and process parameters to compliance with targets (van Schothorst 2005).

PO(s) should be derived from an FSO and act a milestone in the food chain, ensuring the ultimate food safety outcome (Codex Alimentarius 2005a). The concept of a PO with the help of an MRA has been considered a potential option for risk managers to guide in establishing operational process requirements, even in absence of an ALOP or FSO. When establishing a PO, its position and the assumed effects of the subsequent production steps should be taken into account in the food chain. The MRA would help in deciding on the need for a PO and the choice of the proper step for its application. The stringency of a PO should be dependent on the type and final handling of the food in such a way that compliance with the ALOP (and FSO) remains without requirements being too tight. Thus, the PO may be the same as the ALOP, if the frequency and/or concentration of the hazard is not likely to increase or decrease between the point of the PO and consumption (Wallis and Buchanan 2005). If the microbial hazard is likely to grow after the last PO, the PO has to be more stringent, and if the microbial hazard is likely to decrease, the PO may be less stringent (van Schothorst 2005).

The application of the PO concept with MRA has revealed incompatibility with the current PO definition and/or content (FAO/WHO 2006). Accuracy, certainty or general focus are limited with deterministic QMRA, or the unambiguous target of a “maximum frequency and/or concentration” expressed as a PO is lost with a distribution outcome of probabilistic QMRA. The determination of possible PO values has also been considered more difficult with the latter.

Performance and process criteria

Performance and process criteria belong to the risk management measures that are to be applied on the company level in order to carry out functional risk-based food safety management. A **performance criterion** has been defined as the effect on the frequency and/or concentration of a

(microbial) hazard in a food that must be achieved by the application of one or more control metrics to provide or contribute to a PO or an FSO (FAO/WHO 2007). The **process criterion** has an interim definition in meat hygiene (Codex Alimentarius 2005b) as physical process control parameters (e.g. time, temperature) at a specified step that can be applied to achieve a performance objective or performance criterion.

Microbiological criteria, MC

Microbiological criteria (MCs) are to be stated for bacteria, viruses, yeasts, moulds, algae, parasitic protozoa or helminths and their toxins or metabolites (Codex Alimentarius 1997). MCs are not derived from risk analysis but rather from management systems controlling foodborne hazards during food processing determining the acceptability of specific production lots of food (ICMSF 2002). So, there is a relationship between an MC and an FSO (Table 2), but it may not be a direct one (Stringer 2005).

Table 2. *Characteristics of FSOs and microbiological criteria (Stringer 2005, based on van Schothorst 2002).*

Food safety objective	
Aim	A goal on which food chains can be designed so that the resulting food will be expected to be safe
	Aimed at consumer protection
	Applies to food at the moment of consumption
Components	Maximum frequency and/or concentration of a microbiological hazard
	Product to which it applies
Use	Only for food safety
Microbiological criterion	
Aim	A statement that defines the acceptability of a food product or lot of food
	Confirmation that effective GHP and HACCP plans are applied
	Applies to individual lots or consignment of food
Components	Microorganisms of concern and/or their toxins/metabolites
	Sampling plan
	Analytical unit
	Analytical method
	Microbiological limits
	Number of analytical units that must conform to the limits
Use	For food safety or quality characteristics

Nauta and Havelaar (2008) noted that risk-based MCs can be derived by the application of a QMRA model linking the test and sampling scheme directly to an estimate of population health risk. MCs may be used to formulate design requirements and to indicate the required microbiological status of raw materials, ingredients and end-products at any stage of the food chain as appropriate (Codex Alimentarius 1997). An MC may be set by a competent authority or industry, and then implemented as a food safety measure using GHP or HACCP approaches (FAO/WHO 2002). The authorities can use MCs to define and check the compliance of food production with the microbiological requirements, and added to that the food business operators can use them for verification and validation purposes (Codex Alimentarius 1997). An MC should be established and applied only when there is a need for consumer protection that has been demonstrated with epidemiological evidence or with a risk assessment, and when it is technically attainable.

MCs should be mandatory only when no other more effective tools are available and where they are expected to improve the degree of consumer protection (Codex Alimentarius 1997). In the case of non-compliance with a mandatory MC the actions taken are dependant on the magnitude of risk to the consumer, at the stage of the food chain the MC is applied, and on the type of product. Where stated by the operator the MC may be stricter than legally required, and non-compliance should not then lead to legal action.

An MC consists of several aspects: 1) the micro-organisms of concern have to be stated, 2) a qualitative or quantitative analytical method validated and chosen to give a sufficiently reliable estimate, 3) critical limits based on data appropriate to the food, and 4) a sampling plan including the sampling procedure and decision criteria for a lot (Codex Alimentarius 1997).

The EFSA has proposed to the international audience the division of MCs into two categories according to the place of application (EFSA 2007b). This division has been used in the EC Regulation on microbiological criteria for foodstuffs (Regulation EC No 2073/2005). In this, the microbiological criteria concerning the acceptability of food products on the market are termed '**food safety criteria**', whereas '**process hygiene criteria**' provide guidance on and are indicators of the acceptable functioning of HACCP-based food safety systems along the food chain. The terms are considered to help in interpreting the actual function of each microbiological criterion in food chain management in a more understandable way.

Precautionary principle and consumer perception

The precautionary principle allows authorities to adopt and maintain provisional measures on the basis of available pertinent information to protect public health in situations where complete scientific information is absent and available data are insufficient for a comprehensive risk assessment (WTO 1999). As a prerequisite, the measure that has been set according to the principle has to be reviewed 'within a reasonable period of time'. The principle as such has been

considered a form of primary prevention in which action is taken in the absence of sufficient data for a standard risk assessment (Goldstein and Carruth 2004).

The precautionary principle was initially developed in the context of environmental policy in the 1970s, and recognised in the Rio Declaration in 1992 (Goldstein and Garruth 2004; Post 2006). The EU incorporated the principle into the Treaty of the European Union (EC Treaty) in the same year, and regarded it as one of the basic rules for European environmental policy (EC Treaty 2002). From there the scope was widened to human, animal and plant health (EC 2000a) and situated within the context of risk assessment and risk management as a principle to be applied during the risk management phase (Post 2006). The European regulation for general food safety (Regulation (EC) No 178/2002) adopted the precautionary principle as an option open to risk managers when decisions have to be made to protect health but scientific information concerning the risk is inconclusive or incomplete in some way. However, the precautionary principle may be adopted provisionally only, until a comprehensive risk assessment can be conducted.

The actions taken under the precautionary principle have been noted to be either an additionally conservative approach within risk management, or a prerequisite for adopting control measures with a shift in the burden of proof, less stringent weight-of-evidence and maximal control strategies not adapted to the degree of exposure (Goldstein and Carruth 2004). While risk analysis stresses laying out the risks and quantifying them as much as possible, the precautionary principle emphasizes the uncertainty of those risks (Post 2006). Problems in applying the principle have been presented as, for instance, it is a more opaque and ultimately less safe approach to policy making than risk assessment, it does not take into account the full set of risk tradeoffs involved, it does not provide a transparent way to balance and account for different risks, it does not help regulators decide which risks to regulate, and it is not well enough defined to stand up to the body of risk analysis (Post 2006). Precaution has been seen more as a political decision than a scientific one, causing more problems than solutions and leading to wrong prioritisation if proper risk/benefit analysis is not performed (Tuomisto 2004). In contrast to “concern-driven risk management”, RA has been seen as “democracy of science” enabling stakeholders conclude the probable consequences of alternative RM decisions, evaluate the models and judge the input assumptions themselves (Cox 2007).

The application, meaning and weight of the precautionary principle in the EU has differed from that in the US. The use of the principle as an excuse for a trade barrier led to a trade disputes and discussion on the international stage, and guided the decisions made in the Codex Alimentarius (Veggeland and Borgen 2002). European defence considered the precautionary principle a general customary rule of international law or at least a general principle of law, whereas from the US point of view the precautionary principle was an approach with a content varying according to the context (WTO 1998). According to the WTO (1998) the precautionary principle has not been written into the SPS Agreement as a ground for justifying SPS measures, and it cannot substitute scientific risk assessment as a basis for trade-restrictive sanitary measures. However, the concept was agreed to reflect the Preamble of the SPS Agreement with the explanation that responsible, representative

governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life terminating, damage to human health are concerned (WTO 1998).

Although it was stressed that the precautionary principle cannot override any article of the SPS Agreement, consumer perceptions and behaviour have been considered of relevance (WTO 2001). However, the principles and methods for integrating consumer opinions in risk management decisions have not yet been developed to give guidance in defining 'consumers', how their opinions and representativeness should be evaluated, how to consider variation in opinions, or how to confirm that consumers express an informed opinion based on factual and accurate information (Motarjemi and Mortimore 2005). Interpretation of consumer opinions may be difficult, because of differences in risk perception due to the characteristics of risks (Rowe and Wright 2001) and characteristics and experiences of individual persons (Parry et al. 2004, Slimak and Dietz 2006; Hogarth et al. 2007) as well as demographic factors (Cox 2007, de Jonge et al. 2007, Lindell and Hwang 2008). Proactive education has been considered to reduce concerns and unnecessary changes in food consumption habits (Rimal et al. 2001; Röhr et al. 2005), although motivation to prepare safe food has been found a better indicator of actual behaviour than declarative food safety knowledge (Fischer et al. 2007).

Hazard Analysis and Critical Control Points, HACCP

The hazard analysis and critical control points system is obviously the best known food safety management system concerning food industry in the world. The first HACCP requirements had been regulated for canned foods as early as 1973 (Panisello 2000). Based on the Total Quality Management (TQM) philosophy (Sparling et al. 2001) it has been developed and modified in many ways since its early applications in order to confirm safe foods for astronauts in the 1960s (Sperber 2005a). HACCP (Codex Alimentarius 1969 as amended to date) is based on seven principles describing a two-stepped central idea on how to prevent foodborne health risks during manufacturing. First all the hazards that may cause adverse health effects in the end-product need to be identified and evaluated along the process. This step is started with a qualitative 'brain storming' or a sensitive ingredients list in order to identify all conceivable hazards (Sperber 2001), and the significant hazards are then selected for the HACCP plan. A documented control system with management and follow-up is built around the selected hazards. To function effectively, HACCP needs so-called prerequisites, i.e. good hygiene practice (GHP) measures, Codes for Practice where available, as well as compliance with food safety legislation to be implemented in production (Wallace and Williams 2001; Rodgers 2005). The International Organization for Standardization (ISO) developed a standard that combines HACCP and the prerequisites to be applied in any organization in the food chain to facilitate the implementation of food safety management systems in the framework of other management systems (ISO 2005). In 1998 the British Retail Consortium (BRC) introduced its own standards to be used to evaluate manufacturers of retailers' own brand food products (http://www.brc.org.uk/). The BRC standards,

which also cover non-food consumer goods, include detailed instructions and forms to be completed about packaging, storage and distribution, among others.

The implementation of HACCP in food regulation as a requirement has been considered to have a positive influence on food safety (CDC 2003, Aruoma 2007, Cormier 2007), although modifications to the content of the principles (Untermann 1999) and their application (Sperber 2005b) may have been inadequate (Naugle et al. 2006, Celaya et al. 2007). The EU required food business operators in 1993 (Directive 93/43/EEC) to apply five principles "used to develop the system of HACCP". In 2001, seven HACCP principles were required from operators producing and marketing fresh meat, and certain microbiological test procedures were laid down for them (Decision 2001/471/EC). The present EC regulation (Regulation (EC) No 852/2004) lays down general requirements of food safety programmes and procedures "based on the HACCP principles". The HACCP requirements concern all food business operators when feasible.

In 1997, the FSIS modernized meat and poultry inspection towards a preventive approach by regulating the requirement for Pathogen Reduction/HACCP systems (USDA 1996) to be applied in meat and poultry slaughter and processing plants (Buzby and Crutchfield 1997; Kvenberg et al. 2000). Subsequently, a decline in human salmonella cases has been presupposed to prove the efficacy of the regulation (CDC 2004). Unfortunately, the decreasing trend has not continued, but the salmonellosis incidence has remained approximately on the level achieved in 2004 (CDC 2008).

In 1995, Finland implemented an in-house control system, called own-checking, in the Health GHP measures and elements of HACCP, was further implemented in the new Food Act (23/2003), which includes the regulation concerning food safety except that for feeds.

Table 3. *Principles of the HACCP system (Codex Alimentarius 1969)*

Principle 1	Conduct a hazard analysis
Principle 2	Determine the critical control points
Principle 3	Establish critical limit(s)
Principle 4	Establish a system to monitor control of the CCP
Principle 5	Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control
Principle 6	Establish procedures for verification to confirm that the HACCP system is working effectively
Principle 7	Establish documentation concerning all procedures and records appropriate to these principles and their application

HACCP has many interfaces with risk analysis. In HACCP the critical control points (CCP), or more widely taken the critical process steps for relevant hazards are explored, and a system is established to control the process to prevent, eliminate or reduce the risk caused by a hazard, and to respond to the deviations. From the risk analysis point of view, HACCP and HACCP-like systems are regarded as risk management options (Codex Alimentarius 2005a). On the other hand, as risk assessment produces information on hazards linked to possible intervention sites of the food production chain as well as on the effects of interventions, the approach and methods developed are exploitable at the company level. Emerging risks can also be evaluated in a more quantified way on the company level if sufficient information is available and, for instance, critical limits can be based and control measures can be validated on a more durable basis (Notermans and Mead 1996; Hoornstra et al. 2001). Risk assessment has also been seen as profitable for food companies during product development, process optimalization, and validation of the HACCP plan (Hoornstra and Notermans 2001).

Prioritization of the hazards and the choice of relevant CCPs are the fundamental keys for a successful HACCP. Small and medium-sized enterprises (SMEs) in particular have been recognized to have difficulties in HACCP implementation (Taylor 2001). However, with sufficient guidance and support, HACCP is also considered achievable for them (Taylor and Kane 2005, Bertolini et al. 2007). Several tools have been developed to assist companies in hazard analysis with risk assessment measures. Van Gerwen et al. (2000) built the Stepwise and Interactive Evaluation of Food Safety by an Expert System SIEFE, a software system that quantifies risks to support HACCP development. Serra et al. (1999) presented Risk Analysis and Critical Control Points (RACCP) as an application combining risk analysis and HACCP. Ross and Sumner (2002) developed a semi-quantitative tool for ranking and prioritising the risks of diverse food enterprises. Doménech et al. (2008) presented a model for procedure monitoring by assessing the effectiveness of the HACCP. However, the use of all these models always requires care and expertise.

2.1.4 Microbiological risk assessment

Codex Alimentarius has defined risk assessment as a four-step scientifically based process of risk analysis consisting of hazard identification, hazard characterization, exposure assessment and risk characterization (Codex Alimentarius 1999). It can be generally described as a process that identifies adverse consequences and their associated probability (McKone 1996). In food safety, RA can be delineated as “a scientific study of risks” (www.answers.com) having roots in mathematical theories of probability and in scientific methods for identifying causal links (Covello and Mumpower 1985) between adverse health effects and foods. Codex Alimentarius has introduced risk assessment as a key element for governments in assuring that sound science is used to establish standards, guidelines and other recommendations for food safety to enhance consumer protection and facilitate international trade (Codex Alimentarius 1999). The scientifically conducted process and independence from industry, politics and decision making are

emphasised in risk assessment. It has also guided MRA, as nominated in the SPS Agreement, by giving principles and guidelines for conducting an MRA (Table 4). A well-designed MRA has been considered to provide the means to evaluate and compare the effects of different control measures on the public health risk to consumers (i.e., risk per serving) or risk to a country (i.e., risk per annum) on an industry-wide basis (WHO 2007).

Table 4. *General principles for microbiological risk assessment (MRA) (Codex Alimentarius 1999)*

Principle 1	Basis on sound science
Principle 2	Functional separation from risk management
Principle 3	Structured format including hazard identification, hazard characterization, exposure assessment and risk characterization
Principle 4	Clearly stated purpose and output (risk estimate)
Principle 5	Transparency of conduct
Principle 6	Identified constraints such as cost and resources and their consequences
Principle 7	Description of uncertainty and the source of the uncertainty
Principle 8	Use of such data and data collection systems that allow uncertainty of the risk estimate to be determined, and of sufficient quality and precision to minimize the uncertainty
Principle 9	Explicit consideration of the dynamics of microbiological growth, survival and death in foods and of the complexity of the interaction between human and agent following consumption as well as the potential for further spread
Principle 10	Reassessment over time by comparison with independent human data
Principle 11	Re-evaluation as new relevant information becomes available

Microbiological risk assessment (MRA) is a structured, systematic approach to integrate and evaluate information from diverse sources concerning the origin and fate of pathogens along the food chain and to determine the magnitude of public health risks (Lammerding 2006). MRA can be qualitative or quantitative. Quantitative MRA is defined by the Codex Alimentarius (1999) as a risk assessment that provides numerical expressions of the risk and an indication of the attendant uncertainties, whereas qualitative MRA is based on data that, while forming an inadequate basis for numerical risk estimations, nonetheless, when conditioned using prior expert knowledge and identification of the attendant uncertainties, permits risk ranking or separation into descriptive categories of risk. At its best, qualitative and quantitative risk assessments complement each other in the risk analysis (Apostolakis 2004). The four-step risk paradigm (Fig. 4) is most effective in determining the risk of exposure to known levels of a hazard for which an adverse effect can be extrapolated based upon existing animal, ecosystem, or human data. It is far less effective in

predicting whether a new or unusual compound or situation will cause adverse effects, as there is no database (Goldstein and Carruth 2004).

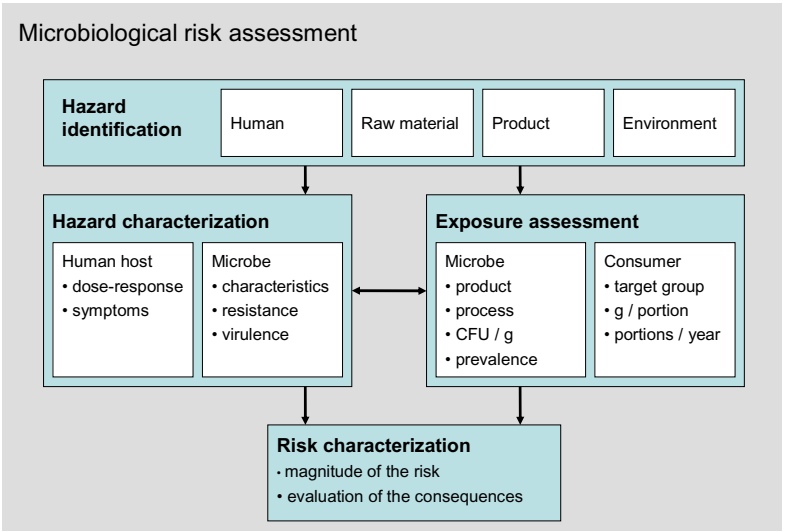

Figure 4. *Components of a microbiological risk assessment according to the Codex Alimentarius Commission (Tuominen et al. 2001).*

The importance of risk assessment lies not only in its ability to estimate public health risk but also in its use as a framework for organizing data as well as for allocating responsibility for analysis (FAO/WHO 1995). As scientific examination of data and factual studies (Principle 1) presented in a structural form (Principle 3), it is not a policy exercise involving social value judgements made by political bodies.

The importance of the transparent (Principle 5) unbiased nature of the MRA process has been emphasized by the requirement for functional separation of risk assessment from risk management (Principle 2). On the other hand, the statement of the specific purpose and the output form of the MRA (Principle 4) need co-operation. Added to that, interaction between risk assessors and risk managers has been considered essential for hazard ranking, risk assessment policy decisions and facilitating risk communication. Efforts have also been made to allow the contribution of interested parties to the MRA. The requirement of identifying constraints caused, for example, by resources (Principle 6) also contributes to the transparency of the MRA.

Based on science, an MRA may use only qualified data in such a way that uncertainty with its sources can be determined (Principles 7 and 8). Concerning the behaviour of microbes, the approach that takes into account the nature of the hazard has to be considered (Principle 9). Verification (Principle 10) and re-evaluation (Principle 11) with relevant data will assure updated knowledge and conclusions provided from the MRA.

The food safety management systems such as HACCP and OCP applied in the food industry are based on hazard analyses that have a lot in common with MRA ideology, i.e. analysing and detecting such hazards and factors triggering risks that are relevant to human health in the process or food chain and then managing them in order to produce food that does not cause adverse effects in the consumer.

2.1.5 Risk communication

As one of the main elements of risk analysis (Fig. 1), risk communication forms a platform for all interested parties to contribute to the risk analysis (Codex Alimentarius 1999). This may improve the transparency and quality of the risk assessment, and facilitate the acceptance of the results of the MRA. The risk management procedures will also benefit from interactive communication (FAO/WHO 1998). Open communication has been considered essential in the identification of social, economic, religious and ethical concerns. The goal of risk communication is to provide meaningful, relevant and accurate information, in clear and understandable terms, to all stakeholders (Billy 2003). It has been confirmed in other areas that high levels of openness associates with lower levels of perceived risks (Chauvin et al. 2007). The safety and confidence of consumers were considered of paramount importance, and open and transparent risk communication was emphasized when stipulating principles and requirements. As a consequence, Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety was enacted, followed by Regulation (EC) No 852/2004 on the hygiene of foodstuffs, Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin and Regulation (EC) No 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption.

Because risk communication is considered an integral part of risk analysis, it should act as a matrix for the whole continuum of the risk analysis process. To react effectively the risk communication strategies should be prepared in advance for all stages and contexts involved. These strategies are needed in both crisis and routine situations. To be effective, risk communication must involve and interact with all interested parties, use trained persons, assure the reception and understanding of the risk communication, and foster transparency during the entire risk analysis process. According to the situation, international, national, industry and local considerations have to be taken into account (FAO/WHO 1998).

Although risk assessment operates on the national level, similar and contributing activities function on the local level. Communicative skills are needed not only in a crisis that leads to recalls but also in the everyday liaison between and within food enterprises, authorities and the public, especially consumers, on every level. Information on risks and their consequences needs to be communicated to all stakeholders, but it is especially crucial to those handling and producing food, because, after all, safe food is dependent on the manner in which food is handled both by the workers in food companies and the consumers themselves. Unsuccessful communicational measures may lead to systemic failures through mistrust and asymmetric information (Hennessy et al. 2003).

2.1.6 The human factor in food safety

In spite of regulation requiring HACCP systems to be in place, some plants may repeatedly produce downgraded products due to improper food safety management (Rasschaert et al. 2007). Small and medium-sized enterprises in particular may be lacking not only money and time but also experience, information, support and interest in food safety management (Taylor 2001). Microbusinesses have been found to have an even poorer understanding of food safety management systems (Fielding et al. 2005). The underlying hindrances to compliance with the regulations may also include a lack of trust in food safety legislation and authorities, a lack of motivation in dealing with food safety legislation and a lack of knowledge and understanding (Yapp and Fairman 2006).

Despite an improved pathogen status of the raw material, the incidence of foodborne salmonellosis may not decrease as expected because, for instance, control in food processing, food service and in homes is lacking (Sumner et al. 2004). Cross-contamination has been considered the predominant risk factor for foodborne illnesses, accompanied by inadequate cooking, slow cooling of food, a lack of refrigeration for several hours, and inadequate reheating before serving (FAO/WHO 2002). In Finland, an infected person who has prepared and contaminated food in the kitchen has been found the most frequently reported cause of foodborne outbreaks (28%), but most other reasons may also be derived from human actions (Fig. 5). According to a recent study conducted in the UK (Clayton et al. 2007), food handlers perceived their business to be of relatively low risk, yet they all prepared high-risk foods. The study supported the argument that sufficient resources and an adequate management system are fundamental requirements for food safety, and the company culture is a helping factor for training efficacy. The concept of risk was considered an important part of food hygiene training. Attitudes and company culture also have an impact on behaviour, and therefore on foodborne outbreaks caused by food workers (Todd et al. 2007).

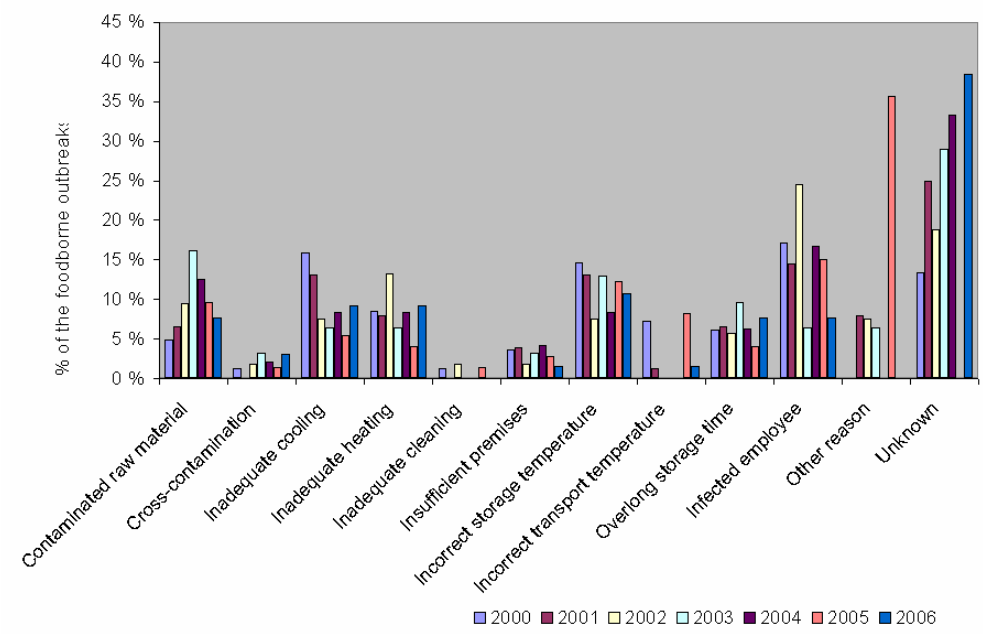

Figure 5. *Risk factors contributing to Finnish outbreaks of foodborne infection during 2000 and 2006 (based on the statistics in Hatakka et al. 2001, Hatakka et al. 2002, Hatakka et al. 2003, Hatakka et al. 2004, Niskanen et al. 2005, Niskanen et al. 2006, Niskanen et al. 2007)*

It has also been discovered that the capacity of the premises (slaughterhouse) does not necessarily correlate with the contamination level, but instead the technique applied, the separation of clean and unclean areas, and controlled movement (Hanson 2000). Proper sanitation actions have been determined as essential when restraining salmonella persistence in the environment and cross-contamination of carcasses in slaughterhouses from day to day (Small et al. 2006). Motivation has been considered a deciding factor in the behaviour of the slaughterhouse workers (Rahkio and Korkeala 1996).

The behaviour of those handling and consuming foods reflects their attitudes, which in turn often results from their education and training. Behavioural studies have analysed the most effective ways to improve risk-based food safety management, although the effect of training may be difficult to assess (Mossel et al. 1998, Wilcock et al. 2004). Targeted training and risk communication should be used in order to change the food handlers' behaviour towards safer food handling and improved knowledge of food safety practices such as cross-contamination, temperature control and personal hygiene (Egan et al. 2007). Training should also cover the consumers in order to tackle the forms of exposure that, for instance, socioeconomic risk factors may promote (Simonsen et al. 2008).

2.2 Salmonella as a foodborne hazard

Salmonella may be found in all varieties of food production, and according to Koohmaraie et al. (2005), the best way to control and eliminate pathogens is to understand their sources and prevalence in the environment. Animal-derived foods have been condemned as the greatest source of human salmonella infections, but more extensive charting, better follow-up and stricter identification are needed to trace the true sources of salmonellosis (Lindqvist et al. 1999, 2002). Furthermore, although control programmes have mainly been targeted towards animal-derived foods, the presence and spread of salmonella should not be underestimated in fresh fruits, vegetables, spices, and aquacultural products (D'Aoust 1994), as also seen in Finnish foodborne outbreak statistics presented in Chapter 3.2.3. (Niskanen 2006).

2.2.1 Characteristics of salmonella spp.

Since salmonella spp. were first discovered in human tissues in 1880, and then isolated from pigs in 1885 by Salmon (Buxton and Fraser 1977), their significance as important pathogens has been recognised. In Finland salmonella was detected for the first time in a fox in 1928 (Stenberg 1958). To date, more than 2,500 salmonella serovars have been identified (Popoff 2004), approximately 2,000 of which are capable of infecting humans. Their host specificity may vary even between variants within a serovar (Wall et al. 1995; Rabsch et al. 2002). Epidemiologically, salmonella bacteria can be divided into human-specific serovars, serovars with host adaptation but also able to infect humans, and serovars able to infect both humans and animals (Jay et al. 2005).

Microbiologically, the genus *Salmonella* belongs to the family of *Enterobacteriaceae*, being an aerobic and facultatively anaerobic, non-spore-forming Gram-negatively stained short rod. Taxonomic dispute over whether the genetic structure or pathogenic consequences should be used as the basis for nomenclature (Crosa et al. 1973, Le Minor and Popoff 1987, Reeves et al. 1989, Euzeby 1999, Ezaki et al. 2000, Brenner et al. 2000, Euzeby 2005) concluded with the phylogenetic approach (Tindall et al. 2005, ICSP 2005). Accordingly, salmonella bacteria are divided into the species *Salmonella enterica* and *Salmonella bongori*, with the former being divided into six subspecies: *enterica*, *salamae*, *arizonae*, *diarizonae*, *houtenae* and *indica*. Most of the bacteria causing salmonellosis in humans and/or animals belong to the subspecies *S. enterica* spp. *enterica*. Serologically, Salmonella bacteria are classified using the Kauffmann-White scheme, according to their somatic surface antigen O, flagellar antigen H and Capsular antigen K. Serovars can be further divided into phage types (PT) according to the bacteriophage, which may be of significance when tracing the sources of an infection. With modern techniques, tracing can also be based on genomic differences.

The optimal growth of salmonella depends on temperature, pH, water activity and nutrient content. The optimum temperature for salmonella is 35-37 °C, but most are able to grow between 7 °C and 45 °C, although slowly below 15 °C (ICMSF 1996). salmonella require a water activity (a_w) of at least 0.94 for growth, although some serovars may survive at a_w 0.43 (Juven et al. 1984). The optimum pH is neutral, in the range from 6.6 to 8.2, but the bacteria are able to grow between pH 4.05 and 9.0 (Jay et al. 2005). The $D_{60°C}$ value for a mixture of 5 salmonella serovars varied from 0.20 to 0.52 minutes (average 0.33 minutes) in beef gravy (Juneja et al. 2003), whereas the D value of a cocktail of 8 serovars in beef at 60 °C varied from 1.29 to 2.94 minutes (Juneja et al. 2001). The $D_{70°C}$ value was determined as 0.25 minutes for a mixture of 6 salmonella serovars in beef patties (Murphy et al. 2002). The Z value for 8 salmonella serovars in meat varied from 6.01 to 7.10 °C (Juneja et al. 2001).

Salmonella is an intracellular pathogen exploiting the follicle-associated epithelium in the intestine, tonsils and lungs in its pathogenesis. The role of bacterial toxins is negligible or unknown. Human-specified *S.* Typhi and *S.* Paratyphi cause severe enteric fever and are mainly transmitted through direct contact, whereas non-typhoidal salmonella bacteria are widespread in animals, the environment and nature, are transmittable through vehicles, and are therefore considered as actual foodborne salmonella. More than 95% of salmonella cases are foodborne (Hohmann, 2001). Rodents and wild birds can act as reservoirs (Davies and Wray 1995, Kapperud and Rose 1983, Refsum et al. 2003), as also can other wild animals (Kruse 2004, Boqvist and Vågsholm 2005). Hosts can become persistent asymptomatic carriers, which facilitates the spread of the bacteria.

Reports on salmonella antimicrobial resistance have been published since the 1960s (Helmuth 2000). Some salmonella bacteria have developed resistance towards one or more antimicrobial drugs following either mutations in their DNA or the transfer of DNA between bacterial strains. This has been considered a result of gratuitous and misplaced use of antimicrobials (WHO 2005). A survey based on isolates from food-producing animals in four European countries during 1999-2001 showed the prevalence of antimicrobial resistance to vary among compounds, hosts and countries (Bywater et al. 2004). Although resistance was higher for older compounds (such as ampicillin and tetracycline) than for newer ones (such as ciprofloxacin, cefotaxime and cefepime), no relationship between use in animals and resistance in humans was evident. In Scandinavian countries a ban on antimicrobial growth promoters for production animals has, however, reduced antimicrobial resistance in animal bacterial populations, resulting in a considerably lower prevalence in these countries (Bengtsson and Wierup 2006). There has been criticism of the statement that restriction of the use of antimicrobial drugs in animals benefits human health (Cox 2007), and that withdrawing animal antibiotic use may cause more days of human illness than it would prevent by increasing the illness rate in animals, the microbial loads in servings from the affected animals, and hence the public health risk (Cox and Popken 2006).

2.2.2 Human salmonellosis

The human incidence of salmonellosis has been estimated at 500/100,000 worldwide (Schlundt et al. 2004). Even an amount as low as 10^0 -10^1 salmonella cells may cause human infection (D'Aoust 1994). The elderly, infants, and the immunocompromised are the most vulnerable to developing illness (Hohmann 2001). Children under 5 years old seem to be in particular danger (CDC 2004). The major symptoms of non-typhoidal salmonella relate to gastroenteritis. The incubation time is 6-72 hours, depending on the host and inoculum. The symptoms vary from asymptomatic carriers to long-term sequelae, most commonly including nausea, vomiting, abdominal cramps, diarrhoea, fever and headache that last about 7 days at the most. Faecal shedding after intestinal infection lasts about 1-2 months, but the status may remain chronic for even longer. Approximately 5% of individuals develop bacteremia and focal infections, including meningitis, septic arthritis, osteomyelitis and joint infections, cholangitis, splenic abscesses, and pneumonia, septic metastases, infectious arteritis and endocarditis (Hohmann 2001), and even pyomyositis has been reported (Minami et al. 2003). An increased tendency for long-lasting digestive symptoms in *S.* Enteritidis patients as a consequence has been reported (Barbara et al. 2000). Antibiotic therapy is not routinely recommended.

According to research on patients with severe salmonellosis and/or prolonged diarrhoea (more than 7 days) from salmonella infection, 1-15% of the cases developed postdysenteric reactive arthritis (ReA) (Locht et al. 1993, Samuel et al. 1995, Mattila et al. 1998, Hannu 2002). In some other investigations the occurrence of ReA was 29%, and the form known as Reiter's syndrome, involving joints, the urinary tract and skin, affected 3% of salmonella patients (Dworkin et al. 2001). The status may persist for even months or years. In Finland, the occurrence of ReA after salmonella infection has been reported to be about 10% (Mattila et al. 1994, Mattila et al. 1998, Hannu et al. 2002).

Salmonellosis caused by resistant salmonella strains has been estimated to be responsible for an almost three-fold higher rate of hospitalization than that due to pansusceptible strains (Varma et al. 2005). Mortality has been reported as 3.1 times higher in patients infected with these salmonella strains (Helms et al. 2003). In Finland, the antimicrobial resistance of salmonella has been followed up epidemiologically since 2000 (Siitonen and Myllyniemi 2006). The proportion of multiresistant strains has remained constant. The endemic *S.* Typhimurium PT1, *S.* Infantis and *S.* Agona are generally sensitive to all antimicrobial compounds that have been tested, whereas *S.* Infantis and *S.* Agona acquired from abroad have been resistant to at least one compound. *S.* Typhimurium PT 104 is multiresistant, whether acquired from Finland or abroad.

2.2.3 Foodborne outbreaks caused by salmonella

The majority of pathogens causing foodborne illnesses are considered to be zoonotic (Käferstein and Abdussalam 1999). The increase in international trade in agricultural, aquacultural and

manufactured food products has facilitated the spread of salmonella (D'Aoust 1994). Salmonella has been the subject of public health concern as an agent causing foodborne diseases for over a century (Hardy 2004). Salmonella has been estimated to be responsible for 30% of the foodborne outbreaks in the United States (Mead et al. 1999), where it was reported to cause approximately one quarter of the hospitalisations and almost half of the deaths among persons with laboratory-confirmed infection (CDC 2004). In Great Britain, salmonella is considered one of the most important pathogens that should be tackled when reducing the number of foodborne cases (Adak et al. 2002). Due to the complexity of its environmental association, salmonella represents a continuing problem for public health (Hardy 2004) and is still considered one of the most important foodborne pathogens (Humphrey 2004). Control of foodborne diseases has been emphasized to be in need of a concerted effort on the part of the governments, the food industry and consumers (WHO 2002).

Besides human suffering, salmonella is also responsible for substantial economic losses. The Foodborne Illness Cost Calculator estimated the cost of all salmonella infections at $2,467,322,866 in 2006 in the US, or $2,343,956,723 when assuming that 95% of the cases are foodborne ($1,766 per case) (USDA 2007). The costs due to foodborne salmonella infections have been estimated to reach €2.8 billion annually in the EU (Byrne 2003). In Finland, the economic losses due to salmonella acquired from broiler meat alone were estimated at €60,680 (€498 per a case) without mortality costs in 2000 (Kangas et al. 2007). Health benefits, estimated either using cost-of-illness calculations or a willingness-to-pay measure from a consumer survey were found significantly larger than the costs of the broiler programme (Maijala et al. 2005a).

Salmonella has also been reported as the leading zoonotic disease in humans in the EU (EFSA 2006b). Reporting of foodborne outbreaks has been mandatory for all EU member states since 2005 (2003/99). According to EU legislation, an outbreak is an incidence of at least two human cases of the same disease and/or infection, or a situation in which the observed number of human cases exceeds the expected number, and where the cases are (probably) linked to the same food source. The burden of salmonellosis has been estimated to vary from 4 to 2,741/100,000 regionally in Europe (de Jong 2006). Most of the human cases in Finland, Sweden, Norway and Austria were reported to have been acquired from abroad (EFSA 2006b). In 2006 there were a total of 160,649 confirmed human salmonella cases, giving an average incidence of 34.6 cases per 100,000 of the population and ranging from zero to 235.9/100,000 in the 24 EU member states, representing a continuous decrease in salmonella cases in the EU (EFSA 2007d). The highest incidences have generally been detected in the age groups 0-4 and 5-14 years. Salmonella has also been one of the main reasons for foodborne outbreaks over the years. In 2006 it was the causative agent of 53.9% of all reported outbreaks, involving 22,705 persons, of which 14.0% were hospitalised and 0.1% died. An average European salmonella foodborne outbreak caused 7 human cases in 2006. *S.* Enteritidis accounted for 55.2% of all cases of a specified salmonella serovar, *S.* Typhimurium (4.1%) being the second most frequent. However, the salmonella incidence has decreased, and in 2005 it was about 10% lower, with 24% fewer salmonella -originated outbreaks than in the previous year.

Eggs and egg products are regarded as the most frequently implicated sources among the foodborne cases of human salmonellosis in Europe, followed in order by poultry, pork, beef and mutton (EFSA 2008). In 2006, for example, there were 1,043 outbreaks with 8,443 human cases due to eggs, 56 outbreaks with 370 human cases due to poultry (including broiler, duck, turkey and other poultry meat as a source) and 15 outbreaks with 185 cases due to pig meat, whereas bovine meat caused 1 outbreak with 20 human cases and other red meat or unspecified red meat products caused 211 outbreaks with 993 human cases, including one sheep meat outbreak (EFSA 2007d). The most commonly reported locations for exposure were private homes (37.3% of the outbreaks with 4,803 human cases) and restaurants (6.8% of the outbreaks with 3,590 human cases). The reported contributing factors have been diverse, including inadequate heating, failures in the storage temperature, cross-contamination during processing as well as deficiencies in personnel hygiene (EFSA 2006b).

In Finland, the incidence of non-typhoidal salmonella during 2000-2007 was 43-56 cases out of 100,000 inhabitants (KTL 2005; KTL 2006, KTL 2007, KTL 2008). About 80% (78-83%) were acquired from abroad (KTL 2008), with an increasing trend (Siitonen 2006). *S.* Typhimurium and *S.* Enteritidis have been the most frequent findings among those acquired from Finland, whereas *S.* Enteritidis has been the most common in cases with a foreign origin, followed by *S.* Typhimurium.

According to Finnish reports, salmonella was among the three agents most often causing foodborne outbreaks in Finland during 2000-2006 (21 outbreaks out of 311), excluding 2003, when there were no food-acquired salmonella outbreaks but one waterborne case (based on the statistics of Hatakka et al. 2001, Hatakka et al. 2002, Hatakka et al. 2003, Hatakka et al. 2004, Niskanen et al. 2005, Niskanen et al. 2006, Niskanen et al. 2007). Within that time period, about 4.3% of all the persons with foodborne illness were infected with salmonella. The responsible serovar has most often been *S.* Typhimurium (67% of the reported salmonella cases and 48% of the outbreaks), followed by *S.* Enteritidis (14% and 24%, respectively). According to the available statistics, approximately 23% of the persons exposed to *Salmonella* spp. in food acquired the illness, *S.* Enteritidis triggering the illness in about 40% (38%), and *S.* Typhimurium in about one fifth (21%) of those exposed.

The number of reported illnesses caused by salmonella outbreaks (mean 17, range 2-68) formed 2-10% of all the reported foodborne cases (and furthermore, 9-63% of those outbreaks reported with an identified vehicle) during 2000-2006 in Finland. In two thirds (65%) of salmonella outbreaks the causative food items remained unknown. Meat and meat products were responsible for about 10% of the cases, whereas in 20% of the outbreaks the source was a vegetable food, which underlines the importance of other sources than animal-derived foods. More than half (61%) of the salmonella outbreaks could be traced to a restaurant or an institutional kitchen. In less than one fifth (17%) of the cases, the exposure took place in a private home.

Salmonella cases are underreported, and in the US, for instance, it has been estimated that only one out of 38 cases are reported (Mead 1999). In Great Britain the reporting activity has been estimated to be 5-10 times higher (Wheeler et al. 1999), whereas according to a Finnish survey

about 10% of human cases are reported (STM 1997). Concluding from a study by Smits et al. (2008), educational programmes might increase the reporting activity of salmonellosis by improving self-confidence in the diagnosis of physicians (Smits et al. 2008).

2.2.4 Salmonella in beef production

Cattle are considered an important reservoir of non-typhoidal salmonella (McEvoy et al. 2003), although not the most important among livestock (Fegan et al. 2004). salmonella has been isolated from beef and dairy cattle at all stages of production (Fitzgerald et al. 2003). Although salmonella is globally widespread throughout the bovine population (Fedorca-Cray et al. 1998), it is quite rare and under control in the Northern European countries of Norway, Sweden and Finland, which have combated salmonella in production animals for decades.

In cattle the symptoms of acute salmonellosis include high fever, diarrhoea, loss of appetite, abdominal pain, depressed milk yield, abortion, and death within 3-9 days. The mortality rate without treatment is 75%. In subacute salmonellosis the symptoms are milder and the prognosis better, although recovery takes 2 months. It may also be a consequence of an activated latent infection localized in the mesenteric lymph nodes, liver, spleen, and gall-bladder, from where the carrier discharges salmonella continuously or intermittently into faeces and occasionally into the milk. Cows calving under an outbreak and heifers are at higher risk of becoming carriers (Nielsen et al. 2004). Lactating cows, especially those in milk for less than 60 days, shed more bacteria in their faeces than non-lactating individuals (Fitzgerald et al. 2003). Volatile fatty acids (VFA) and the low pH in the rumen protect against infection; starved ruminants seem to be less protected (Nesbakken 2005). Young calves sometimes have pulmonary salmonellosis instead of the enteric form. They may also evince encephalomeningitis, polyarthritis and osteitis, and develop gangrene as sequela. Clinical bovine salmonellosis tends to show seasonal patterns.

Overall, *S.* Typhimurium and *S.* Dublin appear to be the commonest serovars isolated from cattle (Wray and Davies 2000), but in Finland *S.* Infantis and *S.* Typhimurium have been the most general findings (Laaksonen et al. 2006). A salmonella dose of $10^4 – 10^{11}$ is necessary to cause infection (Wray and Sojka 1977). However, although the faeces of an infected bovine animal may contain high concentration of salmonella (up to 10^8/g), the concentration in the faeces of carrier cattle may be low (71% <10 MPN/g) and still influence the risk of human salmonellosis (Fegan et al. 2004).

The prevalence data for live animals and herds varies between countries and regions. Surveys carried out have reported prevalences of 21%-31% (dairy herds) (Wells et al. 2001), 31% (dairy herds) (Fitzgerald et al. 2003) 7.4% (dairy cattle) (USDA 2003) and 2.9%-9.1% (beef cattle) (Barkocy-Gallagher et al. 2003) in the US, a prevalence of 0.08% (cattle at processing, 0.004%-0.5% 95%CI) (Van Donkersqoed et al. 1999) in Canada, 2% in Ireland (slaughter cattle, McEvoy et al. 2003) and 6.8% in Australia (Fegan et al. 2004).

In Finland, the apparent herd prevalence has been less than 0.5% since 1990, with exceptions in 1995 (0.88%) and 1996 (0.60%) (Laaksonen et al. 2006). These figures can be considered as worst case assumptions, because they are not based on random sampling, but on sampling mainly targeted at clinical or epidemiologically suspected herds. *S.* Infantis was the most common serovar detected in cattle during 1995-2000, partly because of contamination effect from the large-scale feed-producing factory in 1995. *S.* Typhimurium has been the most often detected salmonella isolation since 2001, whereas *S.* Enteritidis has only been an occasional phenomenon.

Contamination of feed and the environment are considered to have a major influence on salmonella infection in a herd. In Finland the contamination of domestically produced feeds and feed materials intended for animals has annually remained below 1.0% (range from 0 to 0.7%), and below 2.0% (range from 0 to 1.7%) in imports during 1995-2004 (Varimo 2006). Lots with a salmonella status are not allowed to the market.

A feedborne outbreak in the mid-1990s started investigations and a series of actions that involved the authorities, researchers and the industry (Nieminen 1996, Nauholz and Ruoho 1998). In two adjacent municipalities in Western Finland, where the salmonella incidence was especially high, all 245 herds were tested, resulting in 32 salmonella -positive herds (Ruoho 1998). According to the findings, the within-herd prevalence (median 32.61%, range from 2.33% to 86.36%) in the cattle (herd size mean 33.7 animals, range 11-94) correlated negatively with the herd size, an opposite finding to other reported studies (Warnick et al. 2003; Dodson and LeJeune 2005; Callaway et al. 2005). The difference may result from the smaller herd sizes in Finland. The results of two other surveys conducted by a slaughterhouse among its customers showed no correlation between herd size (mean 31.5 animals, range 16-66) and within-herd prevalence (median 10.17%, range from 1.52% to 87.50%) (Hankonen 1996).

Finnish rates for slaughterhouse and meat cutting levels according to the national control programme, i.e. the lymph node, surface swab and crushed beef samples gathered since 1995, presented the highest prevalences in 1995 (0.80%, 0.80%, and 0.64%, respectively), the median of salmonella prevalences during 1995-2005 being 0.16%, 0.11%, and 0.10%, respectively (Laaksonen et al. 2006). The distribution of salmonella serovars detected in foods produced in Finland has followed that detected in production animals, whereas only half of the serovars detected in imported foods have also been detected in Finnish production animals (Kuronen 2006). This suggests that the current situation in Finland may be different from that in Norway one decade ago, when a case-control study showed no association between human salmonellosis and Norwegian domestically produced red meat, poultry or eggs (Kapperud et al. 1998).

Salmonella may cause foodborne diseases via various foods, including vegetables. Animals are the main reservoir; they can shed enterobacteria to their environment and edible plants, for instance, through water supplies. Because salmonella is relatively resistant against environmental conditions like a_w, pH and temperature, it is capable of surviving and growing in meat at the temperatures applied in the food chain, especially after the abattoir at retail and in homes (Koutsomanis and

Taoukis 2005). Recontamination is also presumably a notable but scarcely researched source of salmonella in processed foods (Reij and Den Aantrecker 2004).

In Finland, no salmonella was detected in 130 beef-derived kebab samples gathered from restaurants and producers in 2001 (Johansson 2006). Meat and meat products sampled in Finland during 1995-2005 by local authorities as a part of official control have revealed salmonella in 0.4-1.6% of the samples (Johansson 2006; Niskanen 2006). Unfortunately, the species from which the meat and meat products were derived or the country of origin were not reported.

Antimicrobial resistance of salmonella has not been considered a problem in Finnish cattle. Salmonella resistance against the antimicrobial drugs used for production animals has been followed regularly in Finland since 1983, and with a broader scope through the FINRES-Vet programme since 2002 (Siitonen and Myllyniemi 2006). During 1995-2004 prevalence of resistance was below 10%. In 2003 and 2005 no antimicrobial-resistant salmonella strains were detected in food production animals, and in 2004 only one resistant strain was detected from a pig. *S*. Typhimurium PT 104 has been an occasional finding.

2.2.5 Combating salmonella in the beef production chain

Efforts to combat salmonella already began 40 years ago in Finland, and both regulated and voluntary programmes have been established in order to manage the salmonella risk. Salmonella, with all its serovars, has been a notorious disease in live animals since the 1970s (EFSA 2006b). No trade or movement of production animals from a farm with positive salmonella status have been allowed, and there have been restrictions on the slaughter of animals from such a farm. Feeds have been controlled according to the regulation given in the Feed Act (1998/396), and only negative tested feed lots have been approved for the market. Finland, Norway and Sweden harmonised their salmonella control programmes for certain food production animals and products derived from them, and launched their programmes during 1995 (Hopp et al. 1999). The national Finnish Salmonella Control Programme (FSCP) (MMM 1994) was approved (Commission Decision 94/968/EC) when Finland became a member of the EU in 1995, which brought with it permission for protective actions concerning the export of foods included in the FSCP to Finland (Council Decision 95/409/EC). Denmark launched its salmonella control programme for broilers in 1988, for pigs and pork in 1993 and for layer hens and eggs in 1997 in order to cut the increasing incidence of salmonellosis (Wegener et al. 2003). Great Britain followed by starting salmonella control programmes similar to those of Denmark (BPE 2002).

A need to reduce the incidence of salmonellosis and other foodborne diseases has also been noted in the EC. The EC chose an integrated approach to food safety through farm-to-table measures. salmonella was identified as the priority target in the combat against zoonoses (Regulation EC No 2160/2003), which has led to further actions such as microbiological criteria for salmonella in production and retail (Regulation EC No 2073/2005), restrictions on the use of antibiotics and

vaccines (Regulation EC No 1091/2005), baseline studies on the salmonella prevalence in laying hens (EFSA 2007a) and slaughter pigs (EFSA 2006a), broiler flocks (EFSA 2007c) and turkey flocks (2008) and specified targets for the reduction of foodborne salmonellosis (Regulation (EC) No 1003/2005, Regulation (EC) No 1168/2006, Regulation (EC) No 646/2007). Besides Finland, Sweden and Norway, some other countries have launched salmonella control programmes, and some also for the beef production chain, like Denmark, where the main target is to control *S.* Dublin by serological testing (L. Nielsen Rozenbaum, personal communication 2007). Countries such as Canada (Rajić et al. 2007) and Australia (ADASC 1999), among many others, have started their salmonella control programmes on a voluntary basis. Traditionally, in the combat against foodborne hazards, the European countries have supported an approach that emphasizes proactivity along the whole food production chain (EC 2000b), a strategy that the US has also considered relevant (FDA 2004), instead of targeting the food safety management actions at the end of the food chain.

A food safety management system, whether it is a HACCP, OC or salmonella control system, must be planned, put into practice and maintained over years. This requires commitment, money and a personal capacity. Integrated control programmes have been considered easier to be accepted from the operator's point of view, and market demands would contribute, but scientific evidence on the effectiveness, including cost-effectiveness, needs to be presented (Rajić et al. 2007).

Finnish Salmonella Control Programme (FSCP) for beef production

The aim of the salmonella control programme for cattle is to ensure that the food products derived from cattle are virtually free from salmonella and, in addition, that reliable documentation of the salmonella prevalence is provided (Hopp et al. 1999). The FSCP covers farms, slaughterhouses and meat cutting plants. The precise objective of the FSCP was declared to maintain the salmonella prevalence at no more than 1% nationally and 5% in individual abattoirs and cutting plants (MMM 1994). The strategies to reach the goals were to: 1. prevent salmonella contamination at all stages of the production chain, 2. monitor the production chains at the critical points, and 3. undertake actions necessary to fulfil the objectives when salmonella contamination is detected.

All the herds sending a bull to a semen collection centre have to be examined for salmonella with negative results during a 30-day period before entering the centre, according to the size of the sending herd. The faecal samples have to be examined with an approved test method based on ISO 6579 (ISO 2002) or NMKL 71 (NMKL 1999) (or a test giving equivalent results).

Abattoirs have to take a combined total of 3000 lymph node and 3000 surface swab samples annually, and each (large-scale) slaughterhouse must take at least 59 samples of each. The lymph node samples are to be taken as a sample of 5 lymph nodes from the ileocaecal region of the

carcass. Surface swab samples are taken from two regions of the carcass covering 1400 cm^2 altogether. The number of samples was planned to detect a salmonella prevalence of 1.0% at the population level and 5% at the enterprise level given a test sensitivity of 100%. The sampling has to be carried out in large and small-scale enterprises according to the schedule. These samples have to be taken before chilling, randomly, around the year, and targeted at routine slaughter and processing lines. The results from the beginning of the FSCP until 2007 are presented in Table 5.

Table 5. *Proportion of positive samples taken according to the FSCP for beef production (statistics of Evira and the former EELA)*

Sample	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007*
LNS[1]	0.80	0.24	0.06	0.31	0.16	0.04	0.31	0.06	0.06	0.20	0.10	0.07	0.07
SSS[2]	0.80	0.54	0.22	0.22	0.10	0.11	0.34	0.03	0.06	0.00	0.03	0.06	0.00
CMS[3]	0.64	0.13	0.16	0.07	0.10	0.08	0.20	0.40	0.08	0.04	0.00	0.00	0.00

[1]Lymph node samples [2]Surface swab samples [3]Crushed meat samples *Preliminary result

Measures taken if salmonella is detected include epidemiological investigations, restrictive actions and sanitation measures. The source of the infection/contamination must be traced back if possible. A salmonella -positive farm (having a herd with at least one animal with a salmonella -positive finding) is prohibited from animal trade and transfer, except slaughter according to special instructions and milk for pasteurization, and the prevalence has to be evaluated by testing animals as requested. The diseased animals should be isolated, carriers slaughtered, pests and other animals prevented from entering the shed, and human contacts limited. Cleaning, disinfection and manure handling have to be carried out under the control of the official veterinarian, and protective clothing has to be utilized. The official veterinarian is responsible for informing the slaughterhouse, dairy and artificial insemination centre about the situation at the farm. The restrictive measures are lifted after the herd has been found salmonella -negative twice at an interval of one month.

The slaughterhouse, local authority, municipal veterinarian and county veterinarian have to be informed about a confirmed salmonella -positive lymph node finding. The finding triggers tracing from the slaughterhouse to the farm of origin. The procedure at the farm is the same as described above. If salmonella has been detected from a surface swab or crushed beef sample, the source and the width of the contamination has to be investigated. Extra cleaning and disinfection must take place, and a total of 59 surface swab/crushed beef and environmental samples must be taken and examined within 5 consecutive days. If at least one salmonella positive sample is detected, 59

more samples within the following 5 days are to be taken and examined. The action must be carried on as long as positive samples are detected.

Special guarantees

The special guarantees (SGs) for certain food imports ('additional guarantees' until 31.12.2005) (Council Decision 95/409/EC, Commission Regulation EC No 1688/2005) that Finland gained in the negotiations for EU membership may be considered as trade barriers. They were approved because of the low salmonella prevalence and ongoing national salmonella control programme (FSCP) to protect human health. Export of fresh or minced beef to be sold as fresh or to industrial processes not exceeding 70 °C is only allowed if the consignments are tested for salmonella without detecting it (Fig. 6). According to the SG permission concerning beef-derived products, it is allowed to export processed beef preparations and products, and fresh beef for industrial processes achieving a temperature of at least 70 °C without salmonella testing. Exporting countries with equivalent control programmes are excluded from the requirement.

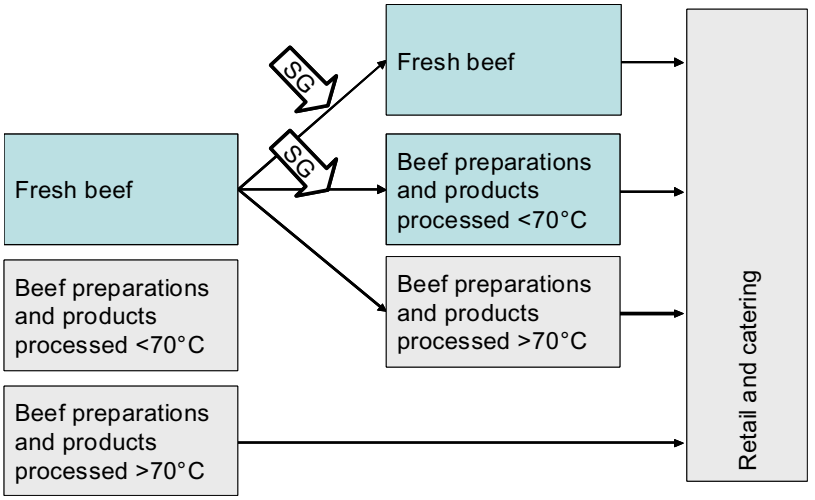

Figure 6. *Special guarantees (SG) for beef-derived foods exported to Finland.*

Salmonella examinations have to be conducted in the country of origin before a consignment covered by the SGs has entered Finland (EC 1995), and the requirement for zero tolerance is in force. If a positive consignment is detected in Finland in spite of the regulation, it must be destroyed, used for other purposes, or returned to the country of origin.

Measurements supporting FSCP

Regulative measures

Production controls and food handler education have been considered an approach to reduce meat borne salmonellosis (Jackson et al. 1991). In Finland, this has been taken into account when regulating the food industry. In 1994, the government made it mandatory for food operators to run OC systems in order to manage food safety (Act on Health Protection 763/1994; Food Act 361/1995). The enterprises handling beef or bovine-derived products had to base their OC plans on HACCP principles and submit them to be approved by the competent authority (Act on meat hygiene 511/94, amended in the Act on food hygiene of foodstuffs of animal origins 1996/1195). The three acts were updated into a new nationally regulated Food Act (23/2006) that comprises the national enforcement and inspection due to EC directives and regulations given in the 2000s on food-related issues (Arvanitoyannis et al. 2005). The new legislation underlined the responsibility of the operator and OC, and urges industry to produce guidelines for implementing HACCP and good hygiene practices. Furthermore, those food workers handling unpacked foods are nowadays required to prove their knowledge by taking a special exam on food hygiene and OC principles.

Both the Feed Act (1998/396) and Animal Disease Act (1980/55) have been exploited in the control of manufacturing and import of animal-derived feed products, and the control of side products has been steered by EC legislation (EC 2002) since 2003. National regulation completes the control by managing plant-derived feed production. In practice, the salmonella control of feed production nowadays lies on HACCP-based OC programmes run by the industry and inspected by the authorities. Every consignment of feed imported from third countries (countries outside the EU) is monitored for salmonella by the authorities, whereas only plant-derived consignments from other EU countries are checked by the authorities, and those of animal origin are checked by the importer as a part of its OC programme (Varimo 2006).

Salmonella has been a notifiable animal disease in Finland since the 1970s, and human salmonellosis since 1995 (EFSA 2006b). The Animal Disease Act (1980/55) requires the investigation of every animal showing clinical symptoms of salmonella or being epidemiologically suspicious. Regarding bovine animals, the whole herd has to be examined for salmonella according to the same procedure as taken when an AI bull is to be sent to a semen collection centre. The restrictive measures triggered if a positive sample is detected are also the same.

EC regulation (Regulation EC No 2073/2005) has set down microbiological criteria for process and retail levels. Carcasses have to be examined after dressing before chilling according to ISO 17604 by swabbing four sites of 100cm^2 (ISO 2003). A result of 2 positive samples out of 50 is considered acceptable, although Member States with a low salmonella prevalence are permitted to set tighter limits. For the retail level the sampling plan includes the requirement of 0 positive salmonella samples detected out of 5 samples of minced meat / meat preparations intended to be eaten raw or cooked, or meat products intended to be eaten raw. Small-scale slaughterhouses and slaughterhouses able to present low rates may be permitted to reduce their sampling frequency. Sampling frequency reduction may also be permitted in regions with a salmonella control programme in place that includes testing, and when a control programme demonstrates a low salmonella prevalence in purchased animals.

The food safety criteria for salmonella in beef and beef-derived preparations and products on the market define a satisfactory lot as a sampling of 5 units with an absence of salmonella according to the method based on ISO 6579. The requirement concerns minced meat and meat preparations intended to be eaten raw (one sample unit = 25g) or cooked (one sample unit = 10g), mechanically separated meat (one sample unit = 10g), and for meat products intended to be eaten raw excluding products with a manufacturing process or composition eliminating the salmonella risk (one sample unit = 25g). An unsatisfactory result shall lead to withdrawal or recall of the product. In case the product is not yet at retail, it may be submitted to further processing by a treatment eliminating salmonella, or to a use other than originally intended.

The process hygiene criteria for salmonella in beef and beef-derived preparations and products are targeted to the slaughterhouse level and defines a lot of carcasses satisfactory if salmonella is detected in at most 2 samples out of 50 samples derived from 10 consecutive sampling session. EN/ISO 6579 is the analytical method to be used. One sample consists of sponge samples referring the minimum area of 400cm^2 per one carcass taken after dressing but before chilling from various sites of the carcass. A corrective action in case of an unsatisfactory result must lead to improvements in slaughter hygiene and review of process controls, origin of animals and of the biosecurity measures in the farms of origin.

Voluntary measures taken by the Finnish beef industry

In certain fields of food production, in-house control has expanded from obligatory OC systems to comprehensive management systems concerning the whole production chains. In the mid-1990s, when a feed outbreak affected Finland, both the dairy and meat industries took responsibility by setting up projects and establishing follow-up systems to screen for salmonella from farm to table. The actions included surveillance of cattle farms (Ruoho 1998; Kouvo et al. 1999) and abattoirs, including transport vehicles (Hankonen 1996). Studies on salmonella dynamics and eradication on the herd level (Aho et al. 1996; Ruoho 1996; Yli-Hynnilä 1996a; Yli-Hynnilä 1996b) and research on sampling methods (Andersin 1997, Kivelä et al. 1999) were also conducted in collaboration

with scientific and governmental partners. The research concluded with instructions for farmers on how to prevent salmonella infections and how to eradicate salmonella from cattle (Nauholz and Ruoho 1998, Yli-Hynnilä and Ruoho 1998). An insurance system was developed for farms to minimize the costs and to motivate in prevention of salmonella (Nikunen et al. 1997).

Official border control and quarantine measures concerning animal imports were lifted when Finland joined the EU, due to free trade and the Community laws. The Finnish industry and producers founded the Association for Animal Disease Prevention (Eläintautien torjuntayhdistys, ETT) in 1994 to protect the good animal disease situation in Finland (ETT 2007). The ETT informs and gives instructions on animals, embryos, semen, and feed import, as well as disease eradication and trade. Salmonella-free feeds were considered one of the most important prerequisites in salmonella prevention (Kortesniemi 1996). Therefore, the ETT also keeps a so-called positive list on companies that prepare or import salmonella -tested feeds or mixed feeds. The ETT has had a significant role in carrying out the sanitation programmes developed for salmonella -positive farms. Nowadays, 95% of Finnish dairies, abattoirs and egg-packing companies are members of the ETT.

Most Finnish dairies and slaughterhouses regularly examine environmental samples from the premises where wastes are stored (O. Ruoho, personal communication, 2007). If salmonella is detected, the transport vehicles are charted, and the source (infected farm) is traced. The insurances for salmonella are included in the quality systems of the dairies and beef processing industry, and available to producers meeting the criteria.

2.3 Quantitative microbiological risk assessment

2.3.1 Quantifying microbiological risks

In order to create a formally structured MRA, all of its four components (Fig. 3) must be included (Codex Alimentarius 1999). Although quantitative risk estimates are encouraged (Codex Alimentarius 1997), both qualitative and quantitative MRAs are accepted as long as the assessment fulfils the criteria set for scientific work, peer review being considered an essential part (Apostolakis 2004). Hazard identification and hazard characterization, except for the dose-response, are usually also carried out in a qualitative manner in quantitative risk assessment, but exposure assessment has been conducted quantitatively and the risk estimate is given in a quantitative form. However, a qualitative assessment may also have quantitative, computational parts. Semi-quantitative exposure assessments also exist (Sumner and Ross 2002). The disadvantages of QMRA may be considered advantages of qualitative MRA: the latter may be conducted with fewer resources, the assessment process may be easier to conduct and understand, and the tools for it are available to everyone. The dividing line between different types of MRA is

not very clear in every case, but because of the different types of results (risk estimates) the approach should be chosen according to the goal and the question framing the risk assessment.

The outcome of the MRA, the risk estimate that consists of the probability and severity of the adverse effects caused by the hazard(s) in question, must include a description of the associated uncertainties (Codex Alimentarius 1997). However, the 16th Procedural Manual defined the output of the MRA as a quantitative estimation allowing the uncertainty and variation to also be expressed in a qualitative form but quantified to the extent that is scientifically achievable (FAO/WHO 2007). The prospective risk estimate therefore quantifies the risk caused to the consumer by the hazard in the product or product group under assessment.

To develop the structure of the assessment, the process with its factors has to be charted and then modelled. A model is a picture reflecting reality, and as such it should not be considered as a detailed replica of the event it is describing. A model has many definitions (www.answers.com), but in the MRA context it may be determined as a schematic description of a system, theory, or phenomenon that accounts for its known or inferred properties and may be used for further study of its characteristics. The properties considered essential must be included to the model in order to study them and their effects, but those not essential may be excluded. An ideal QMRA model would be a compact summation of the chain of events with parameters expressing substantive features of the data, interaction between different factors, and preferably also modelling underlying variables. The final version of the model must usually always compromise some of the desired features.

A model can be qualitative or quantitative, but usually only exposure assessment and dose-response are presented as quantitative models. Quantitative models are mainly based on stochastic or deterministic models. Stochastic models contain random and/or uncertain variables whose values are described as distributions. Thereby, the marginal and joint distributions of stochastic models are often produced as simulations on random single values that are repeatedly sampled, iteration by iteration. Unlike stochastic models, those based on differential equations (deterministic models), e.g. microbial growth models, simulate without variation from fixed, determined parameters, resulting in unaltered results, but stochasticity can be imposed on the deterministic functions. Deterministic MRA has been considered a straightforward method but with disadvantages, such as less accurate information about uncertainty, for example, and a tendency to focus on worst-case situations. Stochastic MRA overcomes these disadvantages, but its challenge has been seen in the expression of the distributional outputs as food safety metrics (WHO 2007).

Building a model is a multi-stage process. Nauta (2001) has divided the framework for quantitative modelling into seven steps (Table 6). The coarse procedure is about the same regardless of the modelling philosophy. The ‘risk question’ with the specified goal (risk estimate) and focus (hazard and food in question) should be defined before starting the QMRA. Then the flow of the microbe/food connected to the defined food chain needs to be described and the stages and properties essential for the QMRA defined. All available data have to be collected and the

mathematical model structured. Before the final risk estimate can be agreed on, the fit of the model and its plausibility should be investigated, if not validated (model criticism). Validation is a process of model criticism that can never prove a model "true" but it can point out some of the shortcomings leading to model improvement. From the statistical point of view, models can only be criticized in the light of empirical data. The approach can either be holistic, considering all data and all unknown model quantities simultaneously (as in a fully Bayesian approach), or considering parameter by parameter based on separate data sources for each. In any case, the available data will limit what models can be estimated and validated. Therefore, models cannot be given or preassigned completely independently of data, or else they remain theoretical constructions without empirical justification. Effectively, data as well as initial assumptions can both suggest specific model choices, which in turn are criticized, leading to an iterative model development from assumptions to model structures contrasted with data, and back to assumptions. The role and treatment of data in the modelling process can differ in emphasis between theory driven and data driven approaches. In the Bayesian context a model is a description of current knowledge and uncertainty, and it is to be updated in the light of new data. Therefore, models should not be taken as given, but rather as a formalized framework that enables knowledge to be quantified (Ranta 2001). In this way, probabilistic (Bayesian) modelling is based on the data, describing the level of (un)certainty achieved by updating the prior with the knowledge (data).

Table 6. *The framework for quantitative microbiological risk assessment modelling (Nauta 2001).*

1	Definition of the purpose, the hazard and the food product. Alternative scenarios.
2	Description of the food pathway with processing steps.
3	Building of the model structure with modules.
4	Collection of data and expert opinions.
5	Selection of the appropriate model for each module
6	Implementation of the available data into the model.
7	Performance of the exposure assessment.

Although resource demanding, QMRA has its advantages, because by providing concrete values and numbers it illustrates the magnitude of the risk and allows intelligible comparison of interventions and different control measures (Nauta et al. 2008, Hurd et al. 2008). With a QMRA the consequences of different scenarios are also available to be quantitatively compared. Risk-benefit and cost-effective assessments, for instance, may be directly modelled on QMRAs, as in the example of Kangas et al. (2007), who estimated that the FSCP for broilers costs €990,400 annually or €0.02 per kg of broiler meat, while the public health costs due to domestic broiler consumption were €60,680 and the savings because of the FSCP €1,638,000.

2.3.2 Bayesian modelling

When examining the quantitative modelling process more closely one can perceive some philosophical differences between various approaches. The most obvious categories are the probabilistic Bayesian school of statistics and standard statistics. The expression 'standard statistics' is used here as a generic name for the other schools of statistics as presented by Berger and Berry (1988). Advances in computing and the limitations of traditional statistical methods have promoted the use of the more than 250-year-old Bayesian approach in quantitative risk assessment modelling (Malakoff 1999). The Bayesian approach can be characterized as a means of rational learning from experience in the face of uncertainty (Spiegelhalter 2004). It states the common-sense principle that updated knowledge combines prior knowledge with the data at hand (Congdon 2005). It follows the idea presented by Reverend Thomas Bayes (posthumously 1763), which has been further generated in the perspective of statistical inference, for example by Laplace in 19th as well as de Finetti (O'Neill 2002), Cox and Hinckley in the 20th century (Ashby 2006). Bayes' theorem can be presented for the cases of two events as

$$P(A \mid B) = \frac{P(B \mid A)P(A)}{P(B)} \qquad (1),$$

where P(A|B) is the posterior probability (updated knowledge) of event A, given event B happens, i.e. P(A|B) is derived for a specified value of B. P(B|A) is the likelihood function for event A for a realized event B, or the conditional probability of B given A. It shall be noticed that the term "likelihood" is used in non-Bayesian statistics to denote likelihood-based inference. P(A) is the prior probability (prior knowledge) of event A expressing uncertainty about A before the knowledge about B (data at hand). At the same time it is also the marginal probability of event A. P(B) is the prior or marginal probability of B and the same time it acts as the normalizing factor ensuring the posterior probabilities sum to 1. The main interest lies in the posterior distribution P(A|B) as a belief about A after obtaining data, and the statement itself provides a solution to the problem of how to learn from data (Bernardo 2000). The above equation (1) can also be written as:

$$posterior\ distribution = \frac{likelihood \times prior\ distribution}{\sum(likelihood \times prior)} \qquad (2)$$

(Congdon 2005). In both equations the denominator is a fixed normalising factor summing the posterior probabilities to 1.

The fact that the model parameters of a Bayesian model may be regarded as random variables unlike the fixed quantities demanded in frequentistic models (O'Neill 2002) allows the holistic study of an event or series of events even when there are no complete data and if nuisance parameters are involved. The goal of the Bayesian inference is to assess the total uncertainty based on all the available data. The inference attained is able to balance the model by completing the data gaps and restraining the multiple use of information caused by overlapping sources, or multiple testing of the hypothesis in classical statistics.

The Bayesian approach is called subjective, because a prior is interpreted to express the state of belief about the quantity of interest the observer has. This belief can be presented as a probability distribution, e.g., characterized by a local and scale parameters (Fig. 7). The probability distribution can be presented as a probability density or mass function where these parameters for their part may be used in the modelling. The best known continuous distribution is the normal distribution, where the local parameter is related to the mean and the scale parameter to the standard deviation. Choosing which distribution could represent the knowledge most accurately, depends on the nature and form of information. When the data set is too complex to be described by a single standard distribution, the variable can be modelled with a probability mixture distribution that is a combination of distributions or using nonparametric models. Broad and flat prior distributions such as uninformative uniform distributions represent uninformative or vague prior knowledge but they can also be used as representatives of "objective" priors, whereas less vague, or peaked distributions express more "subjectivity". On the other hand, these "subjective" priors allow explicit inclusion of knowledge drawn from earlier research and expertise. So, the choice of the shape of the prior distribution is up to the research group – and transparent and open to criticism. When there is an abundance of data, the posterior distribution is only weakly affected by the prior in Bayesian analysis. With diminishing data the posterior distribution will resemble the prior more closely. In both cases, this unfolds in a coherent manner according to probability theory.

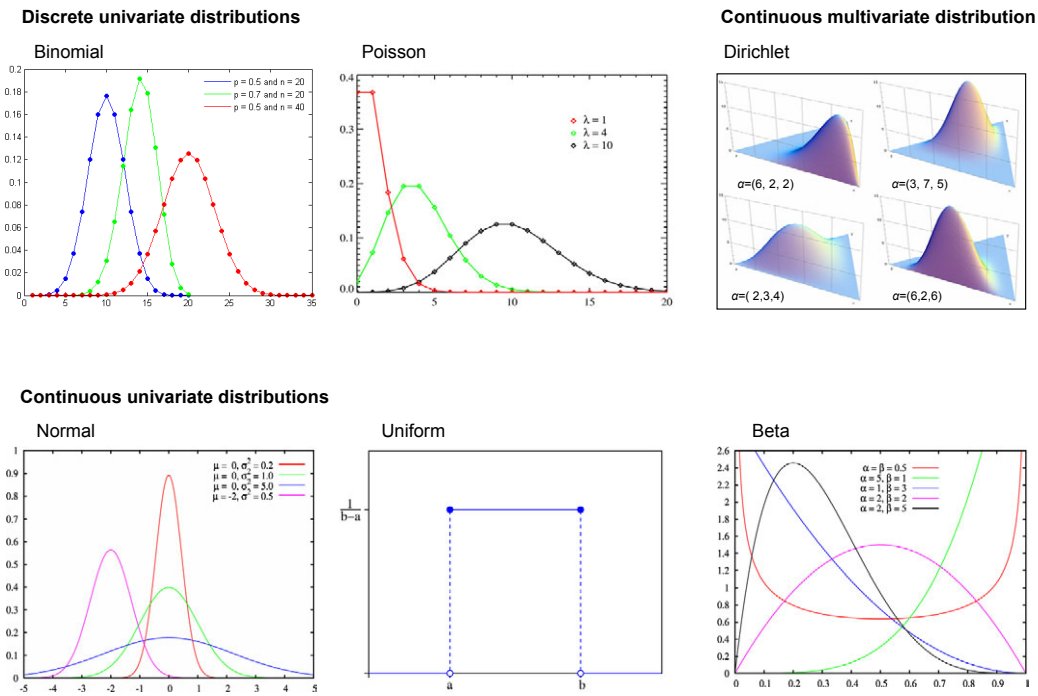

Figure 7. *Examples of some distributions often used in MRA modelling (figures from http://en.wikipedia.org).*

The Bayesian paradigm is based on the idea that posterior information equals the net effect of prior information and data information, i.e., the stronger the prior assumptions the narrower the uncertainty bands (Draper 2007). The uncertainty of the QMRA estimate may result from a lack of knowledge or variance of the event. The model and/or its parameters may include errors and inaccuracies that create uncertainty. The variability of the event itself may also produce varying data. In practice it is often difficult to distinguish these two from each other. However, uncertainty is a requirement of a QMRA risk characterization, but it may be difficult to quantify. The total uncertainty is composed of uncertainty caused by the randomness of the system itself (aleatory uncertainty), the lack of knowledge about the system (epistemic uncertainty), and uncertainty about the model itself (Merrick et al. 2005).

In a Bayesian model, the lack of knowledge can be expressed as the prior distribution of model parameters, and the randomness or the variability of the system as another type of lacking knowledge expressed as conditional distributions of observable phenomena, given parameters that act as place holders for a specific kind of uncertainty within a hierarchical structure of the Bayesian model (Draper 2004). The model performance needs to be judged, for instance by comparing the results with existing data. The credibility of a model describing a phenomenon that

has no observed data to be compared with, e.g. a scenario, has to be validated differently. The rationale of the priors or conditional distributions may be tried by changing their values. The functionality of the model may be evaluated by comparing the subresults for the corresponding data with observations.

A Bayesian model can be presented as a figure (Fig. 8), where a chain of parameters is connected to a net ('Bayesian network') with directed edges (Jensen 2002). A parameter may be determined (the rectangle node in Fig. 8) or conditionally dependant (oval nodes in Fig. 8) on another parameter. The direction of the arrow reveals the conditional dependence. The plate in the Figure 8 represents the part of the model that has the same construction, i.e. common parameters or conditional distributions.

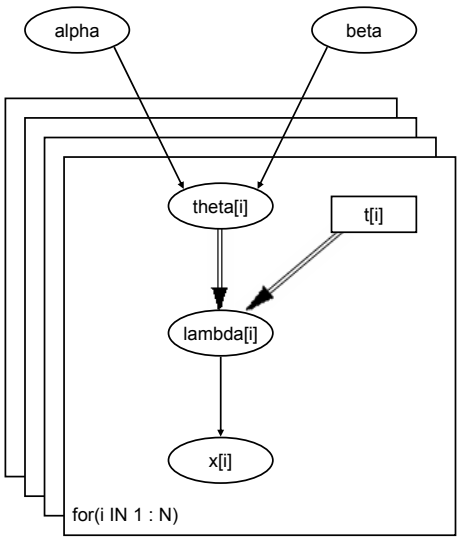

Figure 8. *An example on a Bayesian graphical model (WinBUGS 1.4.1 Help, 2004).*

The principle of Bayesian modelling is simple but the calculation was too time-consuming or was impossible to carry out before the development of modern computers and algorithms. Since the 1990s, progress in this field has been rapid because new devices have been developed. In probability statistics, new simulation techniques have been achieved in order to examine complex systems. For example, with the Monte Carlo (MC) method a large system can be sampled in a number of random configurations, and that data can be used to describe the system as a whole (Woller 1996). Thus, through simulation methodology, Bayesian modelling has become the easiest framework in which to carry out inference in complex models (Spiegelhalter et al. 2004).

MC simulation produces a set of points from which the empirical distribution can be calculated, and this empirical distribution corresponds to the target distribution. The more simulated points there are, i.e. iterations simulated, the more precise the correspondence. It is then possible to calculate parameter estimates such as the mean from the empirical distribution. The MC method is generalized in Markov Chain Monte Carlo (MCMC) methods. Squeezed into few words, the goal of a Bayesian model is to build a probabilistically coherent net of conditional distributions that defines the posterior distribution, and with the help of MCMC techniques produce simulated values for all unknown parameters in the net, given the data.

The most often named advantages of the Bayesian method include transparency of the assumptions included, (holistically) quantified uncertainty, understandable interpretation as well

as flexibility, i.e. the ability to handle complex models and different information sources (Malakoff 1999). Added to that, from the practical point of view, Bayesian analysis tends to favour simple models that explain the data, also manages with small sample sizes, and automatically makes multiple comparisons (Berger 2006).

The Bayesian transparency is composed of various factors. First, the estimation is presented in a compact mathematical model where inference operates towards every direction within the net. Secondly, the state of knowledge and its sources can be traced back by reading prior distributions. The data used for the estimation are also available in the model. All models have subjective elements that may influence the results (Berger 2006). This subjectivity may concern, for instance, the construction of the model and/or input values. However, Bayesian statistics treats subjectivity with respect by placing it in the open and under the control of the consumer of data (Berger and Berry 1988).

The statistical procedures have their own interpretations in Bayesian analysis, which may be easier to understand and explain than the frequentistic ones. The difference can be explained, for example, with the interpretation of the confidence interval used in standard statistics, and the corresponding statistical range in Bayesian statistics, the credible interval. According to the example given by Berger (2006), the confidence interval is interpreted in classical statistics as a confidence procedure C(x) which contains Θ with probability 0.95 if it were repeatedly used with random data from the model for a fixed Θ, and the interval for the given data happened to be (2.31, 4.42). The credible interval, however, is interpreted with Θ that is in the interval (2.31, 4.42) with degree-of-belief probability 0.95. Likewise, the consumers of data want to know how probable it is that the hypothesis is true in light of the data, i.e. the final probability that is produced by the Bayesian posterior distribution (Berger and Berry 1988), but standard statistics gives a p-value as the answer, interpreting it as the probability of obtaining a result at least as extreme as a given data point, assuming the data point was the result of chance alone under the null hypothesis (www.Answers.com).

The flexibility of a Bayesian model comes mainly from the opportunity to build hierarchical models (Fig. 8). They have the capacity to exploit diverse sources of information, to accommodate influences that are unknown or unknowable, and to draw inference on large numbers of latent variables and parameters that describe complex relationships (Clark 2005). Stochasticity is the essential element in Bayesian models by encompassing uncertain and fluctuating factors. Hierarchical models allow the complex constructions to be partitioned into several levels, of which each may include stochasticity and have inference with all the other parameters at the same time. Bayesian philosophy regards the exchangeability from the modeller's point of view according to de Finetti's theorem. If there is limited or no information on the unknown prior or its background, uninformative prior distributions may be the best choice. If, on the other hand, there is some information, this information can be implemented in the prior(s) as a more specified (subjective) distribution that has more influence on the result than uninformative ones have. In Bayesian models, data are always fixed but the unknown or undetected quantities are random.

2.3.3 Models developed for Salmonella risk assessment

Since the method of MRA was launched, quantitative food chain assessments have developed. The model as the summary of the processed data was underlined to act as well as the data, which is why a QMRA should be tested by submitting it to sensitivity analysis (Zwietering and Van Gerwen 2000, Greenland 2001). Salmonella as one of the most important foodborne agents became an object of interest in this field. Microbiological simulation models were advanced for risk assessment use (Cassin et al. 1998; van Gerwen and Zwietering 1998) and the very first salmonella exposure models were published. They concerned *S.* Enteritidis in liquid pasteurized eggs (Whiting and Buchanan 1997), in shell eggs (Baker et al. 1998) and salmonella bacteria in frozen poultry products (Brown et al. 1998). Exposure models without quantification of human association were also published, such as a model of salmonella contamination of pork carcasses during the slaughter process (Berends et al. 1997).

Salmonella Enteritidis on shell eggs and egg products prepared for the FSIS (USDA 1998) was one of the first published MRAs adapting the Codex Alimentarius MRA concept, which still was under development (1999). The goals of the work were to estimate the risk of foodborne illness from *Salmonella* Enteritidis, identify and evaluate potential risk reduction strategies, identify data needs, and prioritize future data collection efforts. The assessment was modelled with five consecutive, independent modules, and the results of the previous module could be exploited as inputs in the following module. When the QMRA was revised in 2005, the dose-response model was renewed and all salmonella serovars were represented (USDA 2005).

A similar modular approach was utilized in the QMRA produced by the FAO/WHO (2002) in the QMRA on salmonella in eggs and broiler chickens. A new dose-response model, representing observed outbreak data, was developed. There was no evidence for the influence of host age or salmonella serotype on the probability of becoming a case according to the outbreak data. The severity of the salmonellosis as consequences or sequelae was excluded because reliable, detailed reports were lacking. Dose-illness models were introduced by Teunis et al. (1999) in order to model the relationship between salmonella dose and illness instead of infection. The idea has been developed further by Bollaerts et al. (2008) with the FAO/WHO model (2002) by taking into account heterogeneity due to differences in host susceptibility, serovar type and food matrix.

Other QMRAs on salmonella in food production chains conducted according to the Codex Alimentarius also started to appear (Ranta and Maijala 2002; Bemrah et al. 2003). The quantification of the source of foodborne salmonella that triggers a human case has been modelled by Hald (2004) and Maijala et al. (2005b), both combining the salmonella -positive findings from production with the consumer risk. The former model stands on its own, processing data from certain animal-derived food production chains including resistant strains and character description of the serovar and food-source. The latter produces the risk estimate by exploiting the assessed food chain estimate for the human data, the variability is included in the uncertainty, and the

resistance aspect is excluded because of the rare occurrence of resistant salmonella strains in Finland. The exposure model for salmonella risk acquired from pork-derived foods (Giovannini et al. 2004) and another from chicken breast fillets (Straver et al. 2007) also took into account the salmonella concentration detected from the samples. The EFSA is starting European-level QMRAs with salmonella in pigs through a consortium of European institutes based on the baseline study already conducted in Member States (Hugas et al. 2007).

Already before the QMRAs concerning exposure on national or international levels, assessments on exposure in industrial processes were initiated in order to develop predictive models for the food industry. Such generic models combine elements of microbiology, mathematics and statistics to develop models that describe and predict the growth or decline of microbes under specified environmental conditions (Whiting 1995). The target of these models has been to assist in hazard analysis and to thereby direct hazard control towards the greatest risks through HACCP programs, and thus enhance food safety management. The risk assessment procedure and HACCP were combined as an RACCP model by Serra et al. (1999). ADP-based programmes like SIEFE (van Gerwen et al. 2000), Seafood Spoilage and Safety Predictor (Dalgaard et al. 2003) and Combase (Baranyi and Tamplin 2004) were developed for industrial use in order to help in quantifying bacterial risks at certain stages of the food chain. Predictive microbiological programs based on models that describe microbial behaviour under different circumstances had already been produced before that, and launched as usable tools, such as the Pathogen Modelling Program by the USDA (1990), the Food Micro model in the UK (McClure et al. 1994), and later on Combase in co-operation (Baranyi and Tamplin 2004). One can estimate the foodborne risk caused by a food company in a semiquantitative way by answering 11 questions about susceptibility and severity, the probability of exposure to food, and probability of food containing an infectious dose in RiskRanger (Ross and Sumner 2002), offered by the Australian Food Safety Centre. The RiskRanger was exploited in association with a qualitative rating scheme presented by the ICMSF (2002) in the identification of food safety risks due to the red meat industry (Sumner et al. 2005). Recently, Ingham et al. (2007) presented THERM (Temperature History Evaluation for Raw Meats), a tool predicting salmonella growth in raw meats, among others. The Swedish food safety authorities are developing a risk classification model for primary production (Anonymous 2008).

The global focus for consumer protection has turned from inspection of end-product acceptability to hazard-based systems that manage processes during food production. The new generation of food safety management systems is targeting an even more proactive goal by optimising public health interventions to allow more quantified actions against threatening hazards in order to protect both the consumers and food producers on international, national and local levels. Both health and cost benefits may be derived from complete/comprehensive management systems with a common goal to offer a nationally or internationally accepted level of protection for public health and consumers. Intermediate measures with which the goal can be directed and/or achieved and the level of protection can be maintained have been modified from older control methods, and completely new measures have also been presented. The accordance of the measures taken or planned with the main and intermediate targets can be assessed with risk assessment and tools based on it.

Although MRA has been developed to reveal the level of risk at different stages of the food chain and thereby assist in risk management decisions, only few food safety management programmes worldwide currently exploit MRA. The capabilities of (Q)MRA have not yet been fully utilised in salmonella management, although salmonellosis is one of the best known and most serious foodborne risks in the western world, and it has been combated for decades with legislation, various control programmes and other actions. The lack of a clear definition for risk-based management has evidently hindered its application, but the lack of tools for governments and food operators as well as the lack of applicable real-life examples has also contributed to the present situation.

3 OBJECTIVES OF THE STUDY

The goal of this study was to examine how risk-based food safety management could be developed both on national and food plant levels. The Finnish Salmonella Control Programme for beef production was considered an example of a national level food safety management system, and the Finnish own-checking system, mandatory for Finnish food operators as a food safety management system including HACCP elements, was exploited as an example of the food processing plant level. The specific aims of the study were:

1. to define the term “risk-based food safety management”;
2. to carry out a quantitative microbiological risk assessment on non-typhoidal salmonella bacteria in the Finnish beef production chain regarding the Finnish Salmonella Control Programme and the special guarantees admitted to Finland;
3. to estimate the true salmonella prevalence along the beef production chain as well as to estimate the salmonella risk caused by fresh beef, beef preparations and beef products available in Finland;
4. to compare beef and beef-derived foods as a source for human salmonellosis with other food products produced under the FSCP;
5. to study the attitudes, practices and knowledge of personnel of food safety management systems at food processing plants; and
6. to generate a tool for food processing plants based on the observations with which their food safety management systems could be developed using microbiological risk assessment.

4 MATERIALS AND METHODS

This research consisted of studies on the evaluation of a national food safety management system with QMRA (I, II, III), and on the implementation of risk-based food safety management systems on the local level (IV, V). An example of the usability and feasibility of QMRA was provided by the assessment of the FSCP concerning salmonella in the beef production chain from primary production (I) up to the consumer (III) with the probable consequences derived from interventions (II, III). The guidelines of the Codex Alimentarius were followed. The practices and attitudes regarding food safety management and its implementation were explored in Finnish food companies (IV) and then taken into account when developing a system that could assist them in developing their food safety management systems towards risk-based management (V).

4.1 National risk-based food safety management – the case of quantitative microbiological risk assessment for salmonella (I, II, III)

As a national level food safety management system, the salmonella risk in the Finnish beef production chain was assessed using a QMRA approach. The target of the QMRA, set by the Finnish Ministry of Agriculture and Forestry (MMM), was to assess the salmonella prevalence at those stages of the beef production chain covered by the FSCP. Furthermore, the influence of the FSCP was to be evaluated at essential stages of the production chain, and its influence on human health on the basis of the QMRA results. The year 1999 was chosen as the default for three main reasons: because the situation was considered stable, because salmonella control due to the FSCP in its entity was already routine, and because there were other salmonella risk assessments in progress based on the same year. The salmonella exposure assessment was conducted with a series of combined mathematical models. They were based on the probabilistic method, exploiting Bayesian inference. The scenarios concerning the impact of the salmonella exposure with and without different interventions were analysed in the same way. In order to compare the different interventions and scenarios, the true prevalence was assessed and used for evaluation.

4.1.1 QMRA models for Salmonella

The salmonella prevalence was quantified with a hierarchical Bayesian model, formed by four quantitative submodels built to quantify the present salmonella prevalence along the beef production chain (Fig. 9). The submodels modelled primary production (Primary Production Inference Model, PPIM), secondary production (Secondary Production Simulation Model, SPSM), imports (Import Prevalence Inference Model IPIM) and consumption (Consumer Inference Model, CIM).

The PPIM assessed the true prevalence of salmonella in live bovine animals, cattle herds and slaughter animals (I). An animal was defined as infected ('salmonella positive') if any of the microbiological tests performed on it revealed positive results, and a herd was defined as 'salmonella positive' if there was at least one salmonella-positive animal in the herd. The resulting posterior distribution representing the true salmonella prevalence in the slaughter animals served as the prior distribution for the following stage of the production chain (Secondary Production Simulation Model, SPSM) (III).

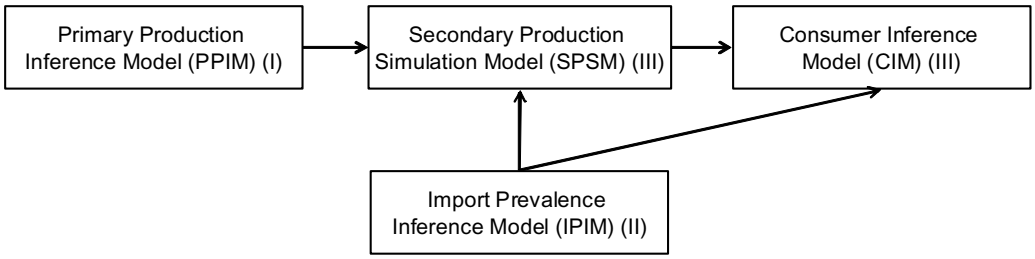

Figure 9. *Models forming the basis of the salmonella risk assessment of the Finnish beef production chain. The models are presented in more detail in Appendix 1.*

The SPSM converted the number of salmonella -positive slaughter animals resulting from the PPIM (I) into the amount of salmonella -contaminated fresh beef. The rise in the salmonella prevalence due to cross-contamination was based on expert opinions. The experts assessed the change in salmonella prevalence during slaughter and cutting, and the influence of salmonella -contaminated raw material on the non-contaminated products during the processes after meat cutting (III).

The assessment of the true salmonella prevalence in imported beef, beef preparations and beef products (the Import Prevalence Inference Model, IPIM) was based on the statistics available from the exporting countries (II). The exporting countries with missing prevalence information were covered with Bayesian inference, in which it was assumed that the salmonella prevalence in every

country exporting to Finland belonged to a population of prevalences deduced from a population distribution common for the exporters. The use of fresh beef imported for industry was considered to be the same as that of the domestic fresh beef. The amounts and salmonella prevalences of the imported beef, beef preparations and products (II) were combined with the domestic results in order to evaluate the total beef-derived salmonella exposure of a Finnish consumer (III).

The SPSM combined the results of the PPIM (I) and IPIM (II) in the CIM (III). The data on the same salmonella serovars detected in both humans and beef production, and the factors affecting the detection of human cases, such as reporting activity, were estimated in the CIM (III). The risk estimate of the whole assessment on the beef production chain was presented as distributions of the number of true human salmonella cases and the number of those reported. All human cases, whether reported or not, were defined as "true cases". The quantified uncertainty was included in the posterior distribution.

The influence of risk management interventions was examined with different scenarios. The impact of SGs was assessed by comparison of scenarios where SGs covered all beef-derived import and where there were no SGs in action (II). The influence of the intermediate objectives on the human cases given in the FSCP was studied with scenarios. In these, the nationwide salmonella prevalence was set to correspond to a prevalence of 1% in slaughter animals, cut beef produced in meat cutting plants, beef-derived import, and beef-derived foods at retail and compared to the *de facto* ALOP (III).

4.1.2 Data and information exploited in the QMRA models

The data and information concerning Finnish circumstances were mainly collected from the results of the FSCP, official statistics and reports of the National Food Agency (formerly EVI, presently the Finnish Food Safety Authority, Evira), the National Veterinary and Food Research Institute (formerly EELA, presently the Finnish Food Safety Authority Evira), the National Public Health Institute (KTL), the Board of the Customs, the European Union (EU), and the Ministry of Agriculture and Forestry (MMM). Some of the lacking information was completed with domestic research performed by the Finnish meat industry, and international studies published in scientific papers.

In the presented QMRA, only prevalences and not concentrations of salmonella were assessed along the beef production chain. The approach was considered acceptable for the goal that was targeted towards the FSCP, which has only given objectives for prevalence without committing on the degree of illness. In the situation with incomplete data the approach was also approved because even a very small number of salmonella cells may cause illness. The CIM estimated the number of human cases on the assumption that there has to be at least one CFU of salmonella per portion of food to cause a human case.

Table 7. *Basic data and information concerning the salmonella QMRA of the beef production chain in 1999. For further details see papers I, II and III.*

Parameter	Value used in the QMRA
Primary Production Inference Model (PPIM)	
Number of cattle herds	30,392
Number of cattle animals	1,086,461
Number of salmonella -positive cattle herds	31
Number of positive results / tests in suspected herds	25/91
Number of positive results / tests in herds sending bulls to semen collection centres	0/160
Number of positive results / own-checking tests in herds	16/5,246
Number of positive results / tests in herds with imported cattle	0/8
Number of positive results / tests of lymph node samples	5/3,104
Laboratory sensitivity for faecal salmonella tests	0.85…0.95
Laboratory sensitivity for lymph node salmonella tests	0.27…0.33
Laboratory specificity for all laboratory tests	1.00
Import Prevalence Inference Model (IPIM)	
Contamination frequency of the beef and beef-derived foods due to the exporting country	Prevalence information available
Fresh beef (as boneless) (kg)	9,458,578
Beef preparations and products <70 °C (as boneless) (kg)	10,726
Beef preparations and products ≥70 °C (as boneless) (kg)	711,669
Laboratory sensitivity for beef and beef product salmonella tests	0.95…1.00
Secondary Production Simulation Model (SPSM)	
Slaughter animal prevalence	Post-distribution from the PPIM
Salmonella contamination frequency in beef and beef-derived foods imported to Finland	Post-distribution from the IPIM
Amount of beef meat produced and consumed in Finland (kg)	68,450,274
Consumption Inference Model (CIM)	
Salmonella contamination frequency in beef and beef-derived foods available to consumers in Finland	Post-distribution from the SPSM
Serving size (g)	122, sd 10
Probability of a true case being reported	0.10…0.30

Table 7 continued.

Parameter	Value used in QMRA
Number of human cases reported in Finland	
Reported number of human cases of domestic origin	566
Reported number of human cases of unknown origin	209
Number of diverse salmonella serovars common both to human cases and the beef-production chain	7

As a whole, the QMRA utilized the available data, relying on as few expert opinions as possible. However, some parts of the beef production chain in Finland essential for the salmonella risk assessment were uninvestigated. These data gaps were filled by expert opinions and some assumptions. The experts involved represented the meat industry, salmonella researchers, epidemiologists and risk assessors, depending on the area in question. The procedure for gathering expert opinions was mainly modified from the principles of the Delphi method (Dalkey 1967). The experts were asked to complete questionnaires including questions formulated to correspond to the missing data. They were required to consider the solutions, results and statistics they had access to in their own work, and to combine this knowledge with the background information acquired from literature, data and statistics. The resulting answers were then combined with distributions representing prior knowledge in the model. Some assumptions had to be made in order to focus and simplify the complex reality of the chain from farm to table.

4.2 Risk-based food safety management in food processing enterprises – the case of attitudes and hazard analysis (IV, V)

One of the aims in this study was to adjust the systems for managing food safety issues in food companies towards a risk-based framework, and at the same time to investigate how risk-based food safety management could act on the plant level. In order to direct the measures and control actions to respond to the relevant food safety risks in accordance with their magnitude, a model for systematic, semi-quantitative hazard analysis was developed for use by those responsible for food safety management programmes, i.e. OCP and HACCP (V).

The approach was chosen in which the GHP and other prerequisites laid down by the Codex Alimentarius (1969) provide the essential basis for a working food safety management system.

Hazard analysis, having a function to prioritize the most relevant risks and to identify the critical steps of the food production process, was identified with the MRA concept. The hazards and hygiene factors that were considered most relevant for the Finnish food industry were recognized as risk factors to be evaluated (Table 8). The four basic parts of an MRA, i.e. hazard identification, hazard characterization, exposure assessment and risk characterization were applied in the hazard analysis procedure included in the food safety management systems practiced in Finland.

While developing the model, attitudes and conceptions of the employees were charted as well as the risk management practices complied in the Finnish food companies in order to respond to the possible needs perceived in their risk management (IV). The knowledge, attitudes and behaviour of the food company employees were studied with a questionnaire survey in order to familiarize the project group with the food processing plants and detect the major needs related to food safety management systems. In 2001, a written questionnaire was sent to 87 Finnish food companies representing meat (23), dairy (21), fish (20) and bakery (23) production. Twenty companies per sector were selected at random, and the seven companies financing the study were added to these. The QA managers of these companies were asked to distribute the questionnaires in their company to the personnel representing QA, finance, line supervision, and production line workers. The coded questionnaires with four pages of questions about the control, education and attitudes concerning food safety management system were sent to each company. The questions were divided into nine categories containing 72 questions demanding 22 qualitative, 21 yes/no and 29 Likert-scaled answers.

The inquiry consisted of questions characterising the respondent as well as canvassing the application and personal conceptions of the implemented own-checking plans (OCP). The activities defined in the OCP were asked about, and the hygiene measures taken in practise were determined. Opinions on the appropriateness, functionality, and necessity of the OCP were also surveyed. In addition, views on the advantages and disadvantages of the implementation of the OCP with the probable consequences were charted.

Table 8. *Food safety hazards and hygiene factors available as modules for assessment in Hygiene Risks Assessment Model Hygram®*

Hazards	Hygiene factors
Aeromonas *B. cereus* *C. botulinum* *C. perfringens* *EHEC* *Campylobacter* *L. monocytogenes* *Salmonella* spp. *S. aureus* *Y. enterocolitica* Moulds	Material factors Constructions Heating, plumbing, air-conditioning Apparatus, device and equipment Water supply Functional factors Maintenance Sanitation Waste management Pest control Cross-contamination Personnel hygiene Immaterial factors Control of operation Training Company culture

The data were analysed with SPSS for Windows v. 11, which was used for the estimation of the significance carried out by chi-squared, ANOVA and t-tests. The questions with missing responses in individual questionnaires were dropped from the analysis, which resulted in varying number of responses to different questions. The non-response bias was not monitored or analysed.

In addition to the questionnaire survey (IV), the food safety regulation, instructions and practices applied in the food industry were investigated in greater depth in 2001 in seven food processing enterprises representing the dairy, bakery, and meat industries. One process was chosen in each enterprise in order to specify and evaluate its food safety risks and risk management by a group consisting of the quality manager, process line supervisor, line worker and three researchers. The study was performed by observing the production line in operation, and by interviewing the quality managers and employees both orally and in written form with the questionnaire described above. The system implementing the OCP that controlled the specific production line was acquainted with the documentation relevant for the study.

5 RESULTS

5.1 Quantitative microbiological risk assessment of salmonella in the beef production chain (I, II, III)

According to the QMRA conducted, the true prevalence of salmonella was clearly under the apparent objective of 1% along the food chain from primary production (I) and import (II) to retail (III) (Table 7). The estimate of the true salmonella prevalence depended considerably on the assumed overall sensitivity of the screening and testing methods, including sampling and pooling practices (I). In the default year of 1999, 31 out of 30,392 cattle herds had a detected salmonella - positive status in Finland. The QMRA estimated the number of herds with a true salmonella status as 5-10 fold higher, being 156-390 with 95% credibility (I).

The lymph node samples taken randomly from slaughter animals revealed an apparent prevalence of 0.16%, whereas the upper level of 95% credible interval of the true prevalence for slaughter animals estimated by the QMRA and deducted from both live and slaughter animal data was up to 2 fold higher compared with the apparent value (0.12 – 0.36) (I). The prevalence of the detected salmonella-positive live animals was not available for the QMRA, but the QMRA estimated the true prevalence to be 0.15-0.39% with 95% credibility.

The different scenarios examined by the QMRA confirmed that the salmonella prevalence of the primary production and raw material has a major influence on the rest of the chain (III) (Table 8).

Table 7. *Estimated true salmonella prevalence in the beef production chain according to the quantitative microbiological risk assessment*

Stage in the beef production chain	Estimated true salmonella prevalence		
	95%CI 2.5% (%)	Mean (%)	95%CI 97.5% (%)
Live cattle (I)	0.15	0.20	0.39
Cattle herds (I)	0.54	0.88	1.36
Slaughter cattle (I)	0.12	0.22	0.36
Domestic fresh beef after meat cutting (III)	0.11	0.21	0.34
Foreign-originated fresh beef at retail (II)	0.02	0.04	0.08

Table 7 continued.

Stage in the beef production chain	Estimated true salmonella prevalence		
	95%CI 2.5% (%)	Mean (%)	95%CI 97.5% (%)
Foreign-originated beef preparations and products (<70 °C process) (III)	0.11	0.21	0.34
Foreign-originated beef preparations and products (≥70 °C process) (III)	0.09	0.64	1.76
Foreign-originated beef, beef preparations and beef products at retail (III)	0.18	0.82	1.67
Domestic beef, beef preparations and beef products at retail (III)	0.08	0.16	0.26
Beef, beef preparations and beef production at retail (III)	0.13	0.26	0.42

Table 8. *Number of estimated beef-acquired human cases of salmonellosis reported in Finland in different scenarios according to the quantitative microbiological risk assessment*

Scenario	Estimated number of reported human cases		
	95%CI 2.5%	Mean	95%CI 97.5%
Default situation	12	87	167
Import without special guarantees	19	116	206
Special guarantees concern all import	10	79	153
Slaughter animal prevalence 1%	66	338	575
Salmonella prevalence of the domestic beef 1%	65	338	575
Salmonella prevalence in beef-derived imports 1%, with special guarantees in force in the default situation	17	99	165
Salmonella prevalence at the retail level 1%, with special guarantees in force in the default situation	78	333	454

The consumer risk for salmonella in beef was based on a comparison of salmonella serovars (Maijala et al. 2005b), and it was assumed that the smallest possible number of reported beef-borne human cases was no cases at all and the maximum number of cases could not have been more than 158 in the referred year (III). The estimated salmonella risk in beef production was compared to the

QMRAs conducted in Finland for salmonella in broiler (Maijala and Ranta 2003), pork (Ranta et al. 2004) and egg production (Lievonen et al. 2006). According to the comparison, beef and foods derived from it formed the greatest source for Finnish consumers (Fig. 10), with pork and pork-derived foods being almost on the same level. Based on the QMRAs, broilers and eggs caused the smallest risk. Imported beef meat, beef preparations and products were, according to the QMRA, as great a risk to the consumers as beef meat, beef preparations and products of domestic origin, even though imports only represented 13% of consumption (II).

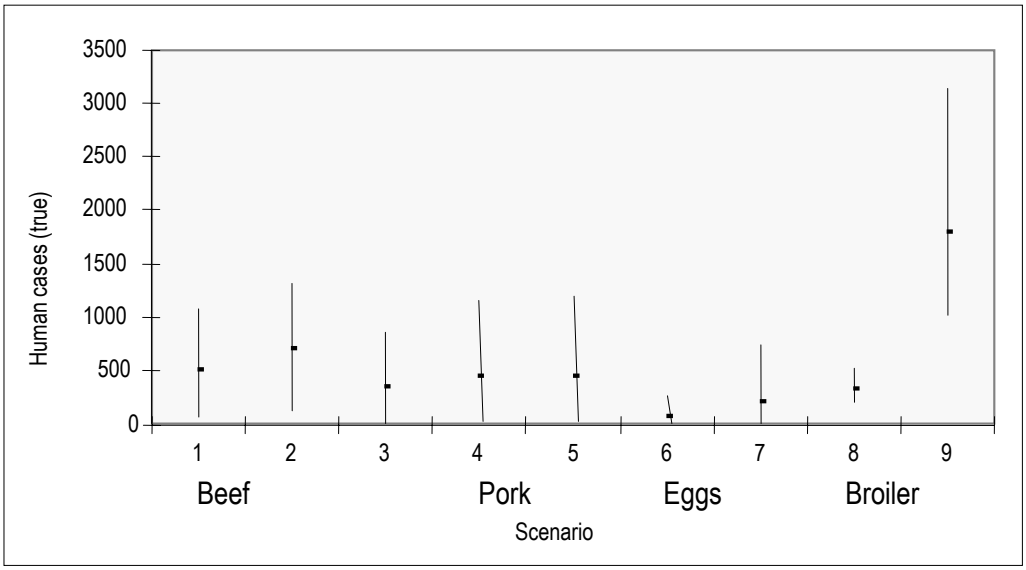

Figure 10. *Estimated number of true human salmonella cases based on the assessment of beef production in this study, and compared to pork (Ranta et al., 2004), egg (Lievonen et al. 2006) and broiler (Maijala and Ranta 2003) production chains adjusted to correspond to the situation in 1999. The main scenarios for the true number of human cases were as follows: due to beef 1) in the default situation, 2) without special guarantees (SG) and 3) with SGs covering all imports; due to pork 4) in the default situation and 5) without SGs; due to eggs 6) in the default situation and 7) without the removal of positive flocks from the food chain; and 8) due to broiler in the default situation and 9) without the removal and heat-treatment of positive flocks. The status is presented as a distribution with the 95% credible interval and the mean is marked as a dot in the line.*

5.2 Assumptions and sensitivity of the salmonella models (I; II; III)

The salmonella models had to be supplemented with some assumptions. In the estimation of the salmonella prevalence in the PPIM (I), the within-herd prevalence was assumed to be similar in all infected herds. An animal was considered as salmonella positive whenever at least one faecal or lymph node sample was detected as positive, although the infectivity status of a lymph-node-positive animal is unclear. The hygiene measures to be taken in the case of a positive salmonella finding were excluded from the assessment because there were no quantifiable data on their effect on farm (I), abattoir or cutting plant levels (III). The assessment of the default situation included all the measures that were in practice, but the efficiency of all the measures could not be quantified.

It was impossible to link the crushed meat samples and surface swab samples to a specific farm. Nor were there any data on the amount of contaminated meat one positive carcass produces. Therefore, the QMRA models probably overestimated the salmonella prevalence in domestic beef by converting a positive animal into a positive amount of beef produced from an average carcass, as if all meat produced from the carcass was contaminated throughout with salmonella. On the other hand, it was also assumed that 70 °C heat treatment destroys all salmonella bacteria from the beef, and only post-contamination may affect the contamination after heating.

The estimate for salmonella -positive slaughter animals based on the PPIM (I) and salmonella -positive lymph node samples was converted to the amount of salmonella in beef according to the approximate carcass weight (II, III). The surface swab and crushed beef samples, which have been set in order to monitor cross-contamination due to slaughter and meat cutting, were excluded from the model. They were not taken into account because they had given approximately similar frequencies to the lymph node samples (Table 5). The probable cross-contamination effects in slaughter and meat cutting in the case of a higher raw material prevalence were based on expert opinions given by the Finnish meat industry (III). Their opinions were founded on the knowledge and experience from their background, but real experience of a situation with a high salmonella prevalence was naturally lacking. Although the part of the exposure assessment modelling the effects of cross-contamination was based on expert opinions, it was firmly attached to the other parts of the whole model supported by statistical data.

The influence of the parameter for cross-contamination (cc) during slaughter was examined by replacing the constant 0.05 with values 1.0 and 10.0, i.e. setting different shapes for the cc curve, and comparing the changes in prevalence. An increase in the cc parameter increases the prevalence of salmonella in domestic products, reducing the relative influence of imports, as expected. The number of human cases remains on the same level as in the default situation. The parameter of cross-contamination at the processing level was first examined by ignoring the threshold value 1%, and then by setting it to 5%. Without the threshold the impact of the domestic raw material would have been one third greater and that of the imported raw material, and 7%

smaller than with the default setting. However, the PO_4 would still have remained below the target prevalence of 1.0% at the retail level (being 0.4% with 95% credibility). With the threshold set at 5% the impact would have naturally been smaller. However, even so, the impact of imported beef-derived foods is considerable given their proportion of consumption.

No specified statistics were available concerning salmonella-tested beef imports to Finland from other EU Member countries (II). Neither was there specified information about the number of consignments that had been rejected due to salmonella detection. For the import with SG requirements (import categories 1 and 2 in the articles II and III) it had to be assumed that the exporting countries with their share of import were the same as those exporting fresh beef according to the statistics of the Board of the Customs, because no nationwide data were available. It was also assumed that the exporters conducted laboratory tests both numerically and methodologically as required. The contamination level of each exporting country was based on the statistics reported by the country itself, and a country without such reported information was considered as a member of "a population of countries exporting to Finland" formed by the countries with information. The prevalence distribution was sampled individually for each country without information from the pool of prevalences reported by the countries with reported information. The method of using hierarchical modelling is presented in more detail by Gelman et al. (2004).

For scenarios it was assumed that the number of human cases varied by the same factor as the number of contaminated servings (III). The severity of the infection was not taken into account, nor was the concentration of salmonella. Because there was no data on concentrations a simplifying assumption had to be made that resulting cases are approximately linearly related to prevalence. The approach can be adequate in situations where the prevalence is low, but may not necessarily be the same in higher prevalence situations.

The focus of the QMRA was the FSCP, which only controls the prevalence. Serovars detected from humans were proportioned to the salmonella findings from food production, assuming that the same serovars may be linked to each other. This provided the basis for the source attribution (III).

Underreporting has been considered obvious, and for the CIM the probability of a detected case being reported was estimated to be 10-30%, based on the results of Wheeler et al. (1999) and an opinion given in a Finnish expert report (STM 1997).

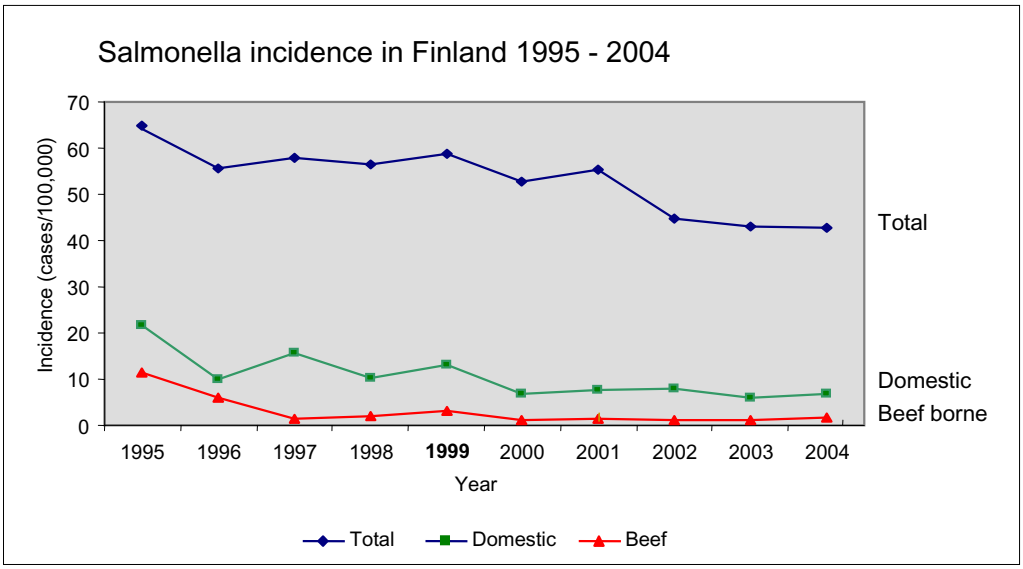

Figure 11. *Reported incidences for total and domestically acquired salmonella cases, and estimates for the beef-acquired salmonella incidence in Finland from 1995-2004. The figures are based on the statistics of the Finnish Public Health Institute, the Finnish Veterinary and Food Research Institute and estimations derived from the Consumption Inference Model (CIM).*

The estimate of the true salmonella prevalence greatly depended on the assumed overall sensitivity of the screening and testing methods, including sampling and pooling practices (I). Test sensitivity was a problematic parameter because there is no internationally accepted gold standard for salmonella (Greiner and Gardner 2000), and sensitivity studies that were available were based on several methods and matrices. The effect on the assessment of the given test sensitivities for the analysis methods ISO 6579 (ISO 2002) and NMKL 71 (NMKL 1999) required by the FSCP and SG was assessed by running the model with different test sensitivity values. In the PPIM, the mean value of the parameter for the laboratory test of lymph node sensitivity was set as 0.30 (Enøe et al. 2001) and for the faecal sample test it was the uniform distribution 0.85-0.95 (Schlundt and Munch 1993, Hoszowski 1989-1990, Andersin 1997, Zdragas et al. 2000, Feder et al. 2001). In order to examine the sensitivity of the model to the test sensitivity parameters, the lymph node test sensitivity was first set to the same level as the faecal test sensitivity, i.e. 0.85-0.95. The model then resulted in the cattle prevalence 95%CI[0.12%,0.30%] with the mean 0.21%. When the test sensitivity for the faecal test was set to 0.3, the true cattle prevalence was 95%CI[0.55%,1.10%] and the mean 0.79%.

The sampling activity outside the FSCP varied in different parts of Finland. The use of the rough estimate for prevalence, dividing the cases detected by all samples taken, might have led to biased results, and region-based activity was modelled for this reason (Heikkinen and Högmander 1994). Targeted sampling that tested animals due to clinical signs or that were suspected for other reasons

found relatively more salmonella-positive animals than random sampling, and confirmed its importance in this way. The cull of dairy animals constitutes a notable proportion of beef produced (Fitzgerald et al. 2003), so the lymph node test results taken randomly at the slaughterhouses were used in estimating both the infected live animals as additional information and the prevalence of salmonella-contaminated beef.

The IPIM and CIM were combined in the SPSM using the WinBUGS program, and also examined with different laboratory test sensitivities (distributions beta[2,2] and beta[2,5]) for meat tests. The value of the test sensitivity was based on an intercalibration survey of food laboratories (C. Wiberg, personal communication 2002) and information available in the literature (Wiberg 1997, Worcman-Barninka et al. 2001, Feldsine et al. 2003, Löfström et al. 2008). A reduction in the test sensitivity priors increased the contamination prevalence of imported meat and meat products, whereas it had only a minor effect on the number of human cases (e.g. the upper limit of the 95%CI of the number of reported cases changed by 0.02%-units and 0.01%-units, respectively). The opposite effect could be seen with an increase in the test sensitivity prior. The values of the laboratory test sensitivities were therefore considered to have some influence on the assessed prevalences along the food chain, but not significantly on the burden of illness. This was regarded as a consequence of the model construction, where the number of reported human cases also steered the risk estimate, correcting the outcome at the same time.

5.3 Food safety metrics for the Finnish Salmonella Control Programme (III)

The prevalence of salmonella in 1995 was considered an objective of the FSCP set by the Finnish government. Therefore, the annual public salmonella status acquired from beef was converted into food safety metrics by combining the *de facto* ALOP directly with the last PO definable in the beef production chain, i.e., with the food portions available for consumers (PO_4).

The FSCP itself covers mainly primary production and primary processing from live animals to fresh beef (MMM 1994). Although the specified FSCP measures concern samples taken according to it (animals/herds with clinical symptoms ($FSCP_1$ in Fig. 12) and herds sending artificial insemination (AI) bulls to the semen collection centres ($FSCP_2$), lymph nodes ($FSCP_3$) and carcass surface swab samples ($FSCP_4$), and crushed meat samples ($FSCP_5$) from cutting plants), the general statement given in the FSCP sets an overall target that the salmonella prevalence/occurrence may not exceed 1% at any stage of the food chain. As a result of the

ongoing FSCP and the low salmonella prevalence, the approved SGs were regarded as a part of the whole beef production chain.

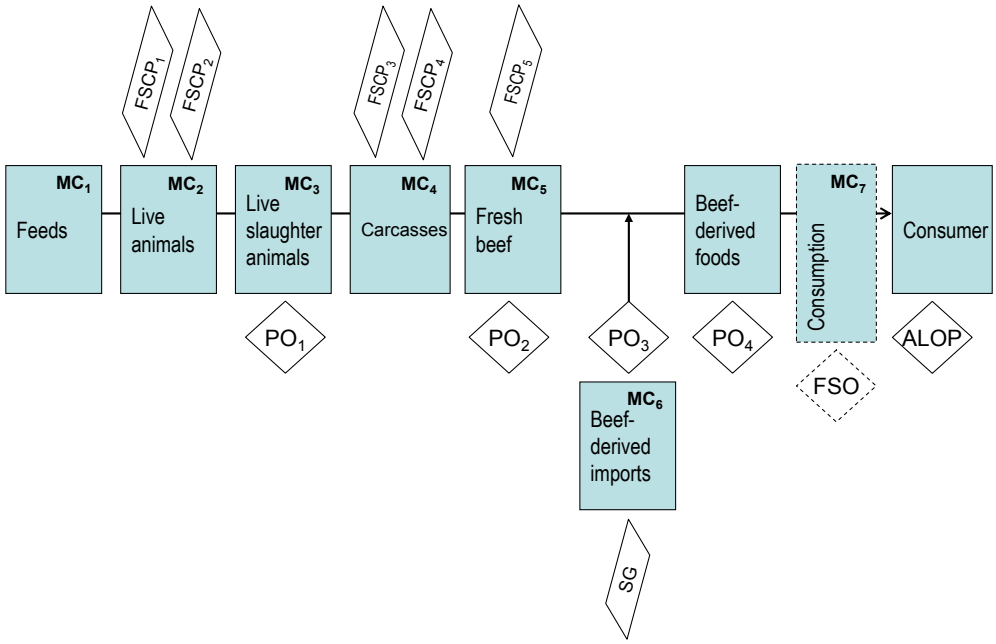

Figure 12. *Overall structure of the beef production chain illustrating the stages covered by the Finnish Salmonella Control Programme ($FSCP_1$,…,$FSCP_5$) and the special guarantees (SG), as well as the sites of the performance objectives (PO_1,…,PO_4). Food safety objectives (FSO) could not be stated but the POs were directly compared with the appropriate level of protection ($ALOP_{de\ facto}$). Stages with microbiological criteria (MC_1,…, MC_7) are also presented.*

In the FSCP, zero tolerance against salmonella expressed at various stages of the beef production chain can be considered as MCs with the limit of non-detectable salmonella in the sample. Any control action as a result of the requirement due to salmonella -positive findings or suspicion of salmonellosis is triggered by exceeding the MC. The requirement for non-detectable salmonella in feeds was considered an MC (MC_1) having influence on the beef production chain, although it is not directly due to the FSCP but other regulations. MCs were included in the FSCP at stages where the zero tolerance was set for AI bulls (MC_2), clinically diseased or salmonella -positive animals (MC_2) and salmonella-positive herds to be slaughtered (MC_3), as well as lymph node (MC_4), surface swabbing (MC_4) or crushed meat samples (MC_5) (Fig. 12). In addition to these, the requirements set for consignments imported according to the FSCP rules were regarded as an MC point (MC_6). The requirement given by the EC for minced beef and beef preparations intended to be eaten cooked was considered the last MC of the chain (MC_7).

The POs were interpreted to stand at the corresponding stages with the control/monitoring points guided by the FSCP (Fig. 12). Besides these, the stages strategic for beef production and health of the consumer were covered by POs. Three POs were therefore defined: for slaughter animals (PO_1), fresh beef at meat cutting plants (PO_2) and for beef-derived foods at retail (PO_4). The core of the SPS Agreement lays down the right of a government to protect the health of the population against greater exposure than that within its borders. The beef-derived food imports were thus considered a PO with a requirement that imports may not exceed a 1% salmonella prevalence (PO_3).

The coherence between the POs and the *de facto* ALOP was not achieved with POs at every level of the beef production chain. For example, a 1% slaughter prevalence could have caused a prevalence that exceeds 1% later in the chain, and besides would not have been able to maintain the *de facto* ALOP. When running the QMRA model with a 1% true prevalence in turn at different PO sites, the POs for the slaughter animal (PO_1) and cut beef (PO_2) resulted in the greatest number of human cases, with the retail level (PO_4) having approximately as great an influence on it.

5.4 Needs for development of the own-checking plan at food processing plants (IV)

The response rate for the questionnaire research was 34.9% out of 87 responding companies, the meat and dairy sectors being the most active. The average number of a responding persons in a company was 200 (range 1 to 1600, median 51). About half of the respondents in every employee group involved expressed a need for more OCP and hygiene training, and the answers given to the questions about the subjects confirmed the same. The number of training hours received during the previous year (mean 8.0 hours and mode 4.0 hours among those 26% who had received training) did not correlate with the degree of need expressed. It became clear that although there was an accepted OCP in all the companies that took part in the survey, the instructions and measures included in the OCP in place were not known by all employees. According to the respondents, audits had also revealed missing documents, a lack of follow-up routine, and deviations in both the content and realization of the food safety system. A lack of time and resources were considered the greatest barriers to the precise implementation and follow-up of the food safety management systems.

In addition to other findings, it was discovered that attitudes towards the OCP were positive and correlated strongly with involvement in the development of the system. Performing control measures that were included to the food safety management system did not seem to improve the opinions about it, but taking part in building and developing it, for instance by writing instructions, did improve opinions (Table 9). The positive correlation between those who had

developed parts of the OCP and knowledge, motivation and appreciation of its contents was clear. On the other hand, the persons developing the OCP were most often those also responsible for food safety, i.e. quality managers and line supervisors, and were thus presumably also more trained in food safety than the other respondents. Furthermore, the opinions of the quality managers and line supervisors concerning the appropriateness of the OCP plan as well as its implementation in practice differed significantly from the group of line workers. The line workers regarded the OCP in practice as less appropriate and more aimed at financial gain than the other two groups. More than half (54%) of the quality managers considered the establishment of an OCP difficult. The most common difficulties from their point of view arose from selecting the CCPs, gaining the commitment of the entire workforce, and organizing the documentation.

Table 9. *Opinions on the current own-checking programmes expressed in the questionnaire survey and their correlation with the background of the respondents.*

	The status of the respondent					The status of the company		
Opinion on the current own-checking programme (OCP)	Handled food	Participated in audits	Had monitoring duties	Participated in OPC meetings	Wrote OCP instructions	Held OCP meetings	Had measures for managing initiatives	Had measures for managing complaints
Appropriate		*	**	**	**	**	*	**
Functioning well		**	**	**	**	**		
Essential		**		**	*	*	**	
Technically difficult		**		**	**	**	**	**
Food safety focused	neg**	**			**		**	**
Economically focused	*				neg*			*
Quality focused		**						
Influences activities		**	*	**	**	**	**	**
Improves food safety		**		**	**	**		*

**Correlation is significant at the 0.01 level (2-tailed). *Correlation is significant at the 0.05 level (2-tailed).

5.5 Modelling hazard analysis (V)

The hazard analysis of the HACCP procedure was considered equivalent to the MRA, but working on the operator level. Based on this consideration, a model applying an MRA-like procedure (Fig. 13) to hazard analysis was developed. Because the model was planned to fulfil the needs noticed in the industry, the information collected through the questionnaires, visits and interviews (IV) were exploited when building the tool. To be in a format where the assessment is easily saved, modified, and disseminated within the company, the model was imported into Microsoft Excel® as an ADP-based spreadsheet tool that was called the Hygiene Risk Assessment Model, Hygram®, and published in 2003 on the WWW sites of the institutes that developed it (EELA, VTT and the University of Helsinki), freely available to be launched after subscription via the Internet.

The risk was determined as a two-dimensional concept referring to probability and severity. To make a clear distinction between GHP and HACCP in Hygram®, the evaluations of the hazards and other risk factors were separated from each other, although both of them were set out in the same framework. The hazards were defined according to the Codex Alimentarius as biological, chemical and physical agents that may cause harm to human health, and the hygiene practices defined according to the Codex Alimentarius were divided into risk factors with the potential to trigger food safety risks. The instructive databank as well as the hygiene and hazard modules (Fig. 13) were modified according to the needs and expectations detected in the questionnaire research (IV). The output of the analysis identifies the most critical process steps related to the hazards or hygiene factors to be noted in the evaluation or development of a food safety management system.

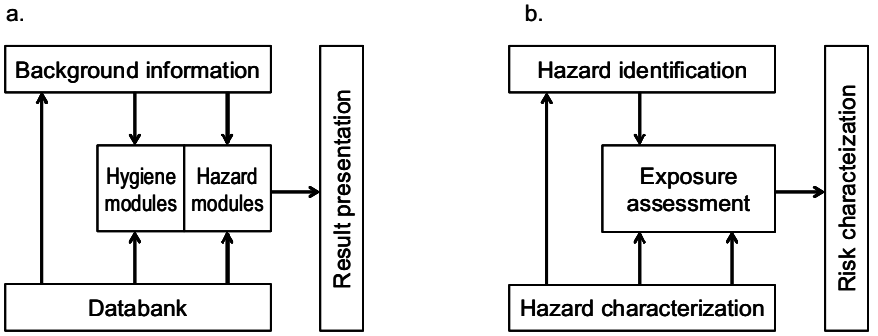

Figure 13. *The construction of Hygram® (a) (V) and the elements of a microbiological risk assessment (b).*

The construction of Hygram® resembles the procedure of MRA. The assessor is guided to assess the probability and severity in the end product factor by factor along the process. The hazards and

the hygiene factors are to be identified against the flow chart first (hazard identification) and then characterized with the help of the databank (hazard characterization). The databank also aids in assessing the exposure in different process steps caused by a hazard or a hygiene factor (exposure assessment). The assessment is performed with selectable modules, and the elaborateness also depends on the demands of the assessor. Optional modules are also available for the model, which provides flexibility in the assessment. The risk factors may be combined or divided, or new factors may be included. The magnitude of probability and severity is to be assessed with a numerical scale bound to descriptive attributes. The results that reveal the points with greatest risk may be observed according to either hygiene factors (or hazards) along the process, or vice versa the process steps along the hygiene factors (or hazards) (risk characterization). The results are presented in both numerical form and figures revealing the elements composing the risk, thus making the necessary decisions clearer for the decision makers.

6 DISCUSSION

Risk-based food safety management is widely proclaimed nowadays, but its content is still undefined by the Codex Alimentarius. Originally, the MRA procedure was developed in order to assess the probability and severity of the food safety risks in a transparent and reliable way, and to establish this assessment on a scientific basis and evidence. Generally, in the area of food safety, 'risk-based control' has begun to stand for anything that concerns action against food safety risks. To be 'risk based', the main target and the intermediate targets of the control programme should compose a coherent entity that is in compliance with the goal at the end-point. In the case of a microbiological food safety hazard, the end-point is always the consumer, and the final goal refers to the goal that has been set for the public health status (public health goal or the ALOP). This cannot be done without MRA. As a consequence, risk-based food safety management was defined in this Ph.D. thesis as food safety management based on risk assessment in order to achieve an appropriate level of protection (ALOP).

MRA has to be used also for setting the food safety metrics that shall be stated in order to produce the final outcome in demand. The assessed magnitude of the risk may influence on how the risks are ranked and thus to the decisions on control measures on both (inter)national and company level. Comparison of adverse effects caused by risks and potential benefits caused by the risk containing foods, i.e. risk-benefit analysis, may need risk assessment for the basis (Tuomisto et al. 2004). MRA can be exploited as a start-point for a cost-benefit analysis as well (Kangas et al. 2007).

6.1 Salmonella quantitative microbiological risk assessment as the basis for risk-based microbiological risk management

The presented QMRA on salmonella in the beef production chain (I, II, III) was established in order to assess the FSCP and its effects on animal and human health. Thereby, the primary production and consumer exposure were modelled in more detail than other parts of the food chain. Because SGs have been permitted due to the FSCP, and they set interventions for imported beef, beef and beef-derived food imports were also included in the QMRA. Exposure to salmonella along the beef production chain was modelled in modules, as had already been proposed in earlier salmonella risk assessments (USDA 1998, FAO/WHO 2002). This procedure

was considered to illustrate the functioning and efficiency of the FSCP, and to estimate the relative impact of the FSCP and SGs on public health.

To assess the effect of the FSCP, QMRA was used to examine objectives related to risk-based metrics such as PO and ALOP in salmonella control. The *de facto* ALOP of the beef chain was defined as the incidence of human salmonella cases acquired from beef, beef preparations and beef products in 1995, when Finland joined the EU and the FSCP was in action for the first year. The QMRA covered all beef-derived foods, from fresh beef to various beef-derived products, offering a diverse matrix for salmonella to survive and/or grow. Hence, an FSO should be a converter between the ALOP and POs. It was impossible to assess even a theoretical objective for the salmonella concentration and/or occurrence that could be accepted as a limit at the time of consumption. It was therefore considered unfeasible to determine an FSO for such a diverse food group, as was also concluded by other risk assessors (Havelaar et al. 2004).

In Finland, the food safety targets included in the FSCP were formulated before the QMRA was conducted. As a consequence, the intermediate targets are not in complete compliance with the public health goal. A risk-based control programme would have been easier to provide by establishing it on the basis of a QMRA, as suggested for *Campylobacter* in the Netherlands (Nauta and Havelaar 2008). In Finland, the public health goal and the intermediate targets had already been stated for salmonella more than ten years ago. Although the *de facto* ALOP was easily achieved, the maximum prevalence of 1% accepted along the beef production chain, i.e. the POs in the study, could not probably have achieved the *de facto* ALOP with 1% prevalence. Zero tolerance along the whole food chain, triggering intervention actions at any stage of beef production when salmonella is detected (MCs in the study), might to some extent manage a situation with a higher salmonella prevalence. Because the effect was not studied in detail, the ability of MCs to resist the impact of significant salmonella prevalences was not predicted here.

Although assessing the risk as very low, the QMRA identified beef to be the greatest source of human salmonellosis cases, unlike on the EU level (EFSA 2008). This could be seen by comparing the QMRAs for salmonella in broiler, pork and egg production chains that have been conducted in Finland with a similar method and assumptions (Maijala and Ranta 2003, Ranta et al. 2004, Lievonen et al. 2006) to the QMRA on the beef production chain (Fig. 10). The order of importance of the sources is similar to that observed in Estonia (EFSA 2005), but opposite to the reports from most other countries in Europe (EFSA 2006b). The result may at least partially be interpreted as a plausible consequence of the interventions and control actions, which differ in the FSCP for beef and pork production from that for broiler and egg production. The control programmes for eggs and broiler production have clear interventions with monitoring and heat-treatment of meat/eggs and destruction of live salmonella-positive flocks already before they or their products enter the food chain (MMM 1994, revised for poultry, poultry meat and eggs in 2007), whereas the control programmes for beef and pork mainly involve random sampling at the slaughterhouses and cutting plants with trace back and other backward measures intervening in the spread of detected salmonella. Without the FSCP, broiler meat could be the source causing most human salmonellosis cases out of those acquired from the food chains under the FSCP (Fig. 10).

The results may also reveal the effectiveness of different FSCPs to some extent. The efficiency of a salmonella programme for pork in Norway similar to that in Finland has also been criticized by Sandberg et al. (2002) and Kruse et al. (2004) for not protecting consumers significantly because of its low probability of sampling a salmonella-positive herd, and targeted herd-based sampling was suggested as an improvement.

According to the QMRA, imported beef meat, beef preparations and products formed as relatively great a risk to the consumers as the beef meat, beef preparations and products of domestic origin, even though imports only accounted for 13% of beef consumption (II). This was especially because of the beef and beef-derived imports without SG requirements. With the current exporting countries and the minor proportion of imported beef consumed in Finland, there was little difference whether the SGs covered all imports, a proportion of them or none (Fig. 10). However, the number of human salmonella cases could rise considerably if the consumption of imported beef-derived foods grows, the variety of exporting countries changes, and/or the salmonella prevalence in the default exporting countries increases.

In reference to Occam's razor, it was concluded that the complexity of the model and the number of parameters should be in balance with the amount of data. A simple model was to some extent was considered better than a complicated model with less essential information, or with such detailed information that might bias the entity. Model simplification has also been regarded as a useful method regarding the scope and purpose of the QRA in the European forum (EC 2003). However, to become a routine method for measuring the annual risk estimate and source attributes, the QMRA should be developed further with an effective data acquisition system.

The Bayesian probabilistic approach with uncertainty that could be included was considered a workable method. Its ability to combine different types of information to handle gaps in data (EC 2003), as well as in this case also different parts of the food chain, and still produce coherent results in the QMRA was appreciated. However, the method was not considered practical as such for general management use, but should be implemented in tailored and easy-to-use ADP programs. Criticism over the difficulty of applying the method because of the distributional results was not considered acceptable. On the contrary, the Bayesian method builds up the estimates by taking into account uncertainty and variability that always exists. In this study the 1% prevalence limit as an accepted salmonella level was regarded as a prevalence of up to 1% with 95% credibility.

Regardless of the aim to conduct the QMRA in such a way that is uses qualified data from research, surveys and statistics, various measures for dealing with data gaps (EC 2003) had to be exploited in this salmonella QMRA. A more detailed quantitative model of the beef production chain would have needed more information on different levels of the chain. In the presented QMRA, valid prevalence data were limited or absent at some stages, and existing knowledge of cross-contamination was poor. For example, the salmonella prevalence of beef-derived foods available to consumers was mainly based on the results from the entire QMRA and limited information on the salmonella prevalence in beef products at Finnish retail. Furthermore, cross-

contamination on the slaughter and processing levels had to be modelled according to expert opinions.

Different serovars were not weighted, as Hald et al. (2004) did in their source attribution model, because no such information was available on the human response in Finland and because all serovars are controlled in the same way in the FSCP. Neither was antimicrobial resistance modelled separately, because of the low prevalence of resistant strains in Finnish production animals (Bengtsson and Wierup 2006). However, because of the different resistance status in the countries potentially exporting to Finland (Kunze et al. 2008, Little et al. 2008), the influence of the resistant strains in imported foods should be carefully recognized in future QMRAs.

The simplified serovar-based deduction of the salmonella sources which was used as the basis for the source attribution may confound the model because of the ubiquitous character of salmonella bacteria (Baird-Parker 1990). Epidemiology exploiting novel laboratory techniques should be utilized in order to define the source of salmonellosis more specifically. The significance of the bacterial concentration to the salmonellosis risk has also been underlined (Straver et al. 2007), but in Finland, which the presented QMRA covered, salmonella rarely occur in any production chain and the concentration figures are presumably small. The QMRA was based on the fact that a contaminated portion must contain at least one salmonella cell, and the model calibrates the assessment with the help of the dose-response model (FAO/WHO 2002) according to the information about reported human cases.

The sources of human salmonellosis acquired in Finland are presented in Figure 10 as separate estimates of the four salmonella QMRAs conducted in Finland. Because the QMRAs have been carried out with similar assumptions and the level of strictness in the modelling has been similar, the relative estimates are comparable. However, the figure could be fine-tuned by including the inference between the food chains and the salmonella serovars in a combined model. More information should be obtained on the frequency, concentration and behaviour of salmonella broadly throughout the food chains, and studies on test and sampling sensitivities are especially needed. In order to allow practical follow-up and to direct the *de facto* ALOP and POs in a risk-based way, future models should combine the dynamics of the FSCP and the most critical stages of the food production chain. Because of these facts, basic prevalence and cross-contamination studies designed to produce unbiased findings should be encouraged.

Estimates may be based on laboratory results, and prevalence would then be presented as apparent. This would be a straightforward way to make evaluations with release from the uncertainty of the test sensitivity. However, use of true instead of apparent prevalences in this QMRA allowed the utilization of results from sampling with diverse sensitivities. This, for its part, enabled hierarchical models and a compact and consistent exposure assessment utilising the underlying dynamics. Thus, stages with absent or weak data could be implemented by exploiting overlapping information from other, better known parts.

The QMRA conducted here provides the basis for future risk and cost-benefit analyses. The public health losses due to beef-acquired salmonella infections can already be assessed from the results of the QMRA, given the assumptions and the cost of €498 per human case determined for broiler-induced human salmonellosis (Kangas et al. 2007). On this basis, the true health costs from salmonella in beef and beef-derived foods available in Finland without death cases may have been approximately 3.6-fold higher than the health costs induced by broiler salmonella (€216,281 vs. €60,680). Because the FSCP for beef differs significantly from that for poultry, the costs of the FSCP must be calculated before the cost-benefit ratio for beef can be assessed.

6.2 Adapting hazard analysis for a risk-based approach

In order to enable risk-based food safety management throughout the food chain, there have to be tools for every level. Although risk assessment is for governmental bodies, a similar approach and tools are also possible for food operators, both big and small. The development of a hazard analysis-type procedure known from HACCP towards MRA allows the development of the food safety management system and follow-up of the targets set by MRA.

With the semi-quantitative Hygram® model a food safety manager can assess food safety risks that may occur in food production in order to help in choosing the critical control points (CCPs) and therefore adjust hazard analysis towards a risk-based approach. The model assists in clarifying the magnitude of the food safety risks, in evaluating the functioning of the food safety management system in place, and in training not only for HACCP, OCP and hygiene management but also for risk-based consideration. Although not representing a system based directly on risk assessment, the model may be used in adapting and/or maintaining the critical limits combined with the CCPs according to the risk management measures developed by a risk assessment. The risk management actions taken on the grounds of this model may therefore be, according to the approach, risk-based or HACCP-based (Codex Alimentarius 1969).

Conducting of the whole procedure involves a hygiene and/or hazard analysis with documented rationales, assumptions and limitations. Hence, the approach and purpose of the model differ from those of the SIEFE, whose aim was to construct a model that assess risks quantitatively for expert needs (van Gerwen 2000). Hygram® also differs from the RiskRanger (Sumner and Ross 2002) by focusing on the exposure caused by food manufacturing, whereas the RiskRanger was developed to rank different operators according to their production.

In the questionnaire survey conducted in 2001 among food industry employees when developing the Hygram® model, large-scale food plants were evidently more representative in the questionnaire survey than the small and medium-sized plants. For example, the respondents represented food plants with approximately 50 employees, which is notably more than in an

average Finnish company in the food industry with less than 20 employees (VNS 2005). This may have resulted in more informed answers than if the respondents had represented average enterprises, given that larger companies with more human resources have supported OCP development and training more than the smaller ones. In spite of the conceivable bias, the results showed congruent opinions both generally and within the employee groups. In response to questions about the barriers to developing or implementing the OCP, the lack of time and resources were mentioned as major hindrances, as has also been noted in surveys conducted in other countries (Gilling et al. 2001, Azanza and Zamora-Luna 2005).

The questionnaire survey was repeated in 2006, five years after a hygiene qualification was regulated for food-handling employees, with a response rate of 33% (Tuominen and Virtanen 2007). All the responding companies had an OCP in place, and 96% of the respondents had a certificate of knowledge on food hygiene and OCP as compared to the 2% in the 2001 survey. The attitudes towards OC were still very positive, although the difference between those who had received training and those who had not was clear, indicating that training has a positive impact on attitudes. The problems in creating and/or developing a food safety programme were the same as earlier: hazard analysis, the lack of commitment, and documentation. According to the responses, it was most difficult to implement the OCP requirements practically but still effectively. The proportion of those trained as well as the amount of training received had increased and so had the proportion of those satisfied with the training compared with the results of the 2001 survey. The proportion of the dissatisfied had respectively decreased. Those who had received training during the previous year were significantly less content with OC training than hygiene training (the proportion of those dissatisfied with OC training was 30% and with hygiene training 12% compared with the 2001 figures of 39.7% and 28.8%, respectively). As a conclusion, hygiene training was considered more appropriate than six years earlier, but the companies should invest more in OC training, because training and a better level of knowledge have been shown to improve food safety practices (Henroid and Sneed 2004). A study on the relationships between attitudes, behaviour and microbial reduction regarding *Campylobacter* in broiler meat showed the efficacy of behavioural cues in training consumers towards safer food handling (Nauta et al. 2008). Such research integrating approaches from both natural and social sciences is needed for all stakeholders in the field of food safety (Anderson and St. Hilaire 2004).

Based on the questionnaire surveys and feedback collected from the users of Hygram®, an updated version of the program was launched in 2007 with modules and databank information about food-associated viruses (norovirus), chemical and physical hazards, and traceability (http://www.evira.fi/portal/fi/el__intauti-_ja_elintarviketutkimus/riskinarviointi/hygram/ or http://www.vtt.fi/proj/hygram/index.jsp). Guidance for HACCP (or OCP) development is available and an existing food safety programme can also be evaluated. The new version does not need other programs to function but works on its own as an independent ADP program. During the years Hygram® has been available it appears to have provided an illustrative tool for education, since it has been launched for educational and research purposes as well as for OCP development. Analysis conducted with the same criteria, for example by the same assessor group, may be considered comparable. Thus, a company may prioritize its resources for food

safety management, as well as allocate them effectively towards the processes and process steps with the greatest risk. Although Hygram® was developed as a tool particularly for use by those responsible for food safety management systems such as OCPs on the company level, it has also been utilised in data collection for MRAs.

Hazard analysis also has similarities to MRA in that it reveals the most probable and severe hazards, but other considerations are needed for making decisions about their management. The control measures must be evaluated, as must their economic consequences. Hygram provides an aid to food operators in conducting hazard analysis by detecting critical stages of the process. The new version also guides the establishment of a management programme. If food safety metrics, such as POs, performance criteria or process criteria exist for different stages of the process, the assessment could carried out directly against them, and the OC (or HACCP) system could thereby be examined with Hygram® as a risk-based food safety management programme.

7 CONCLUSIONS

1. A risk should be assessed or ranked against an end-point, in this case against the health of the consumer. The MRA procedure was originally developed in order to assess the probability and severity of the food safety risks to the consumers in a transparent and reliable way, and it includes the demand for establishing the assessment on a scientific basis and evidence. MRA should therefore form the basis for establishing sound risk-based food safety management for microbiological hazards. Risk-based food safety management should thus be defined as "food safety management based on risk assessment in order to achieve an appropriate level of protection (ALOP)".

2. A quantitative microbiological risk assessment was conducted covering the beef production chain in Finland from live animals up to the salmonella risk to public health. The Bayesian probabilistic approach, with uncertainty that could be included in the inputs and that was available in the results, was considered a dynamic method for QMRA. Its ability to combine different types of information as well as in this case also different parts of the food chain, and still produce coherent results in the QMRA, was appreciated. However, the method was not considered practical as such for routine use, but should be implemented in tailored and easy-to-use ADP programs for decision makers on different levels. Although resource demanding, QMRA had advantages, because by providing numerical estimates it illustrates the magnitude of the risk and allows a comparison of the effect of different control measures on the public health risk. With a QMRA the consequences of different intervention scenarios could also be quantitatively evaluated, and in the future, risk-benefit and cost-effective assessments could be modelled directly on QMRAs. On the other hand, a qualitative MRA may be conducted with fewer resources, its assessment process may be easier to conduct and understand, and the tools for it are achievable to everyone.

3. According to the QMRA, the salmonella prevalence was very low at every stage of the beef production chain, and it was far below the limits (1%) stated for the POs in the FSCP. However, the assessment indicated that the objective (1%) for imported beef and beef-derived foods was probably exceeded. The imported beef-derived foods were estimated to cause as many human cases as domestic beef and beef-derived foods, although the imports accounted for only 13% of the annual consumption in Finland. A change of the consumption of imported beef and beef-derived foods or in exporting countries in the import profile could

even increase the consumer risk. The results of the scenarios suggest that if all the import categories were covered equally with special guarantees, the present level of consumer protection could also be provided with a different import profile.

4. Compared to the QMRAs conducted in Finland for broiler, egg and pork production chains, beef was estimated to trigger the most human salmonellosis cases. Pork was estimated to cause an almost equal risk, but beef was estimated to cause about 25% more human salmonella cases than broiler meat, and about twelve times as many as eggs. This result might partially be interpreted as a plausible consequence of the different interventions and control actions due to the different control programmes in each production chain, and may also to some extent reveal their effectiveness.

5. The personnel in the food industry were found to have a positive attitude towards food safety systems, but the knowledge, training and involvement of those employees directly operating on the site where the control actions take place were found deficient. Further OC training is particularly needed. In practice, the lack of time and resources was found to act as a barrier to the implementation of HACCP/OC programmes.

6. The generic semi-quantitative hygiene risk assessment model Hygram®, developed specifically for small and medium-sized food enterprises, assists in understanding, training, and detecting the relevant hazards and critical steps of the food manufacturing process and thereby contributes in the development of the food safety management systems towards risk-based management. Whenever the critical limits of the process have been defined according to a risk assessment, Hygram® can be used as a risk-based management tool. Otherwise, it works as a tool for hazard analysis and CCP detection when establishing a food safety management system.

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APPENDIX

Graphical descriptions of the main points in the quantitative models developed for exposure assessment to the QMRA concerning FSCP in beef production.

I Primary Production Inference Model (PPIM)

The PPIM model assessed the salmonella prevalence of Finnish cattle herds, animals and slaughter animals (I). The model estimated the initial salmonella level of the domestic raw material, and this result was exploited as the input on the next level of the QMRA.

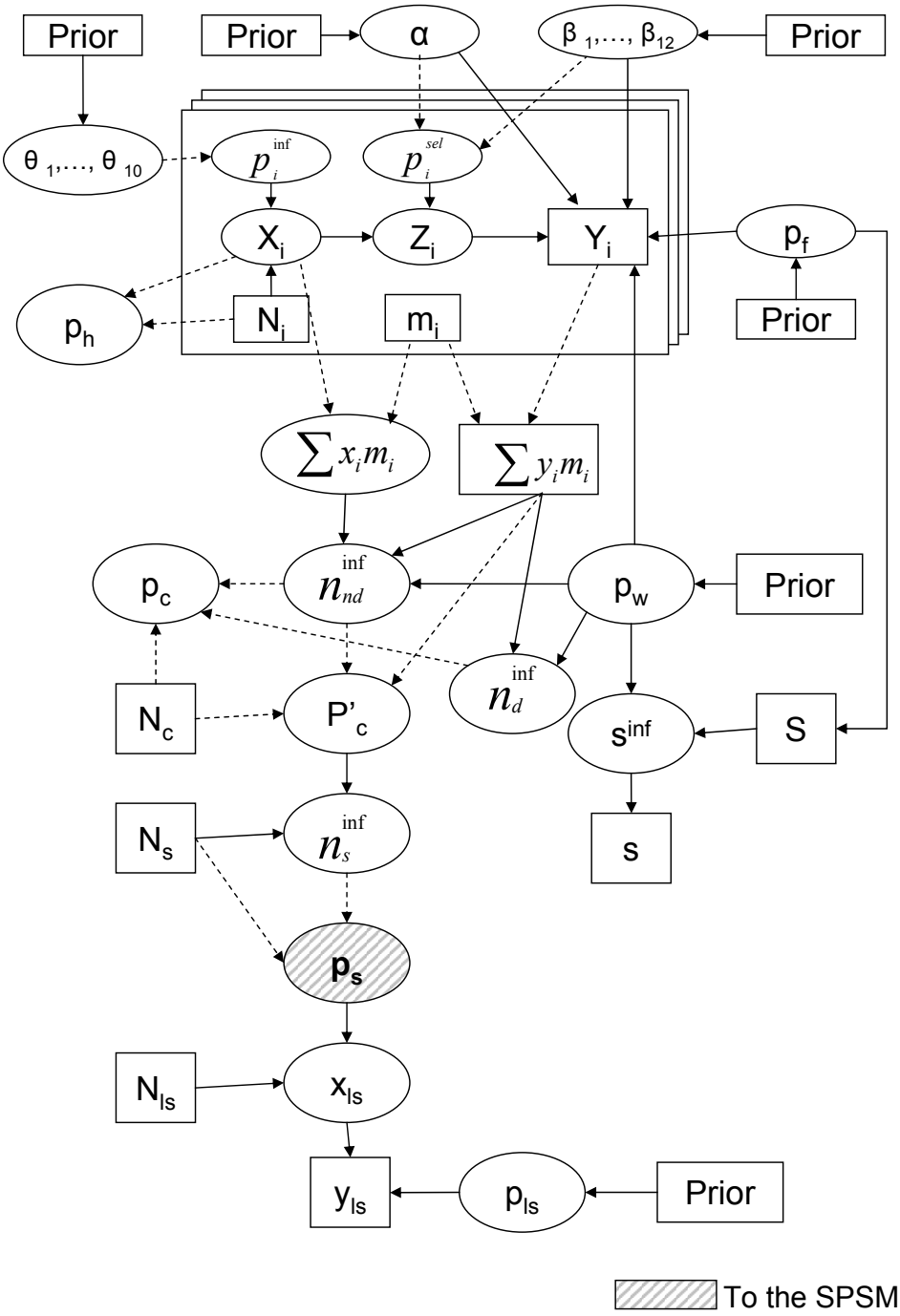

Figure 14. *Graphical presentation of the Primary Production Inference Model (PPIM) for primary production.*

Explanations to the notations in Figure 14:

α	Conditional probability of selecting a herd for testing due to CS, if infected
β	Conditional probability of selecting a herd for testing due to NCS, if infected, in i^{th} municipality
θ_j	Conditional probability of being a salmonella-infected herd in a municipality belonging to the j^{th} cattle density class
m_i	Average herd size in the i^{th} municipality
n_d^{inf}	True number of infected animals in detected infected herds
n_{nd}^{inf}	True number of infected animals in infected but undetected herds
n_s^{inf}	True number of infected animals (cattle) slaughtered
N_c	Total number of cattle animals
N_{ls}	Number of animals tested in lymph node sampling
N_i	Number of cattle herds in the i^{th} municipality
N_s	Total number of annually slaughtered cattle
p_c	True salmonella prevalence in living cattle
p_c'	True salmonella prevalence in all herds that were not detected as positive
p_f	Sensitivity of the laboratory analysis method for faecal samples
p_h	True salmonella prevalence in the herd population
p_i^{inf}	Conditional probability of being a salmonella-infected herd in the i^{th} municipality, i.e., θ_1, θ_2,… or θ_{10}
p_i^{sel}	Conditional probability of being selected for testing, for each infected herd in the i^{th} municipality
p_{ls}	Sensitivity of the laboratory analysis method for lymph-node testing
p_s	True prevalence in the slaughter animal population

Explanations to the notations in Figure 14 continued

p_w	Expected within-herd prevalence in an infected herd
s	Total number of detected positive animals in the additional studies in western Finland
s^{inf}	True number of infected animals in the additional studies in western Finland
S	Total number of animals in the additional studies in western Finland
x_i	True number of infected cattle herds in the i^{th} municipality
x_{ls}	True number of infected animals among the lymph-node-tested animals
y_i	True number of infected cattle herds in the i^{th} municipality (apparent)
y_{ls}	Number of detected positive lymph-node-sampled animals (apparent)
X_i	Number of truly infected herds in the i^{th} municipality
Y_i	Number of herds that become tested positive in the i^{th} municipality
Z_i	Number of infected herds that become tested in the i^{th} municipality

II Import Prevalence Inference Model (IPIM)

The IPIM was constructed to assess the salmonella risk in the beef and beef-derived products imported from other countries for Finnish retail as well as beef-derived raw materials imported for use in the Finnish food industry (II). Fresh beef and beef products were assessed separately but with a similar model.

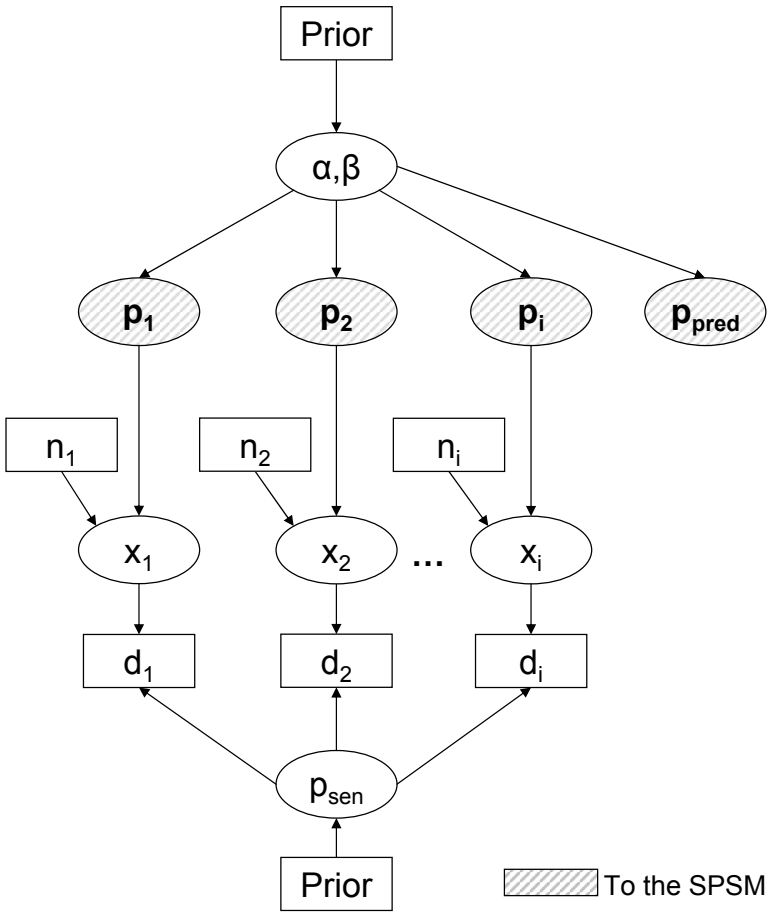

Figure 15. *Graphical presentation of the Import Prevalence Inference Model (IPIM) for imported beef and beef-derived foods. The resultant true salmonella prevalence in the imports is combined in the Secondary Production Simulation Model (SPSM).*

Explanations to the notations in Figure 15:

α,β	Parameters for Beta-density of the specific prevalence of the exporting country
p_i	True salmonella prevalence in the imports from the i^{th} country
p_{pred}	Predicted salmonella prevalence for imports with missing data
n_i	Sample size from the i^{th} country
x_i	Number of salmonella positives in a sample
d_i	Number of salmonella positives detected in the sample
p_{sen}	Test sensitivity

III Secondary Production Simulation Model (SPSM)

The SPSM model assessed the salmonella prevalence of beef and beef-derived products at retail in Finland by combining the PPIM and the IPIM (III).

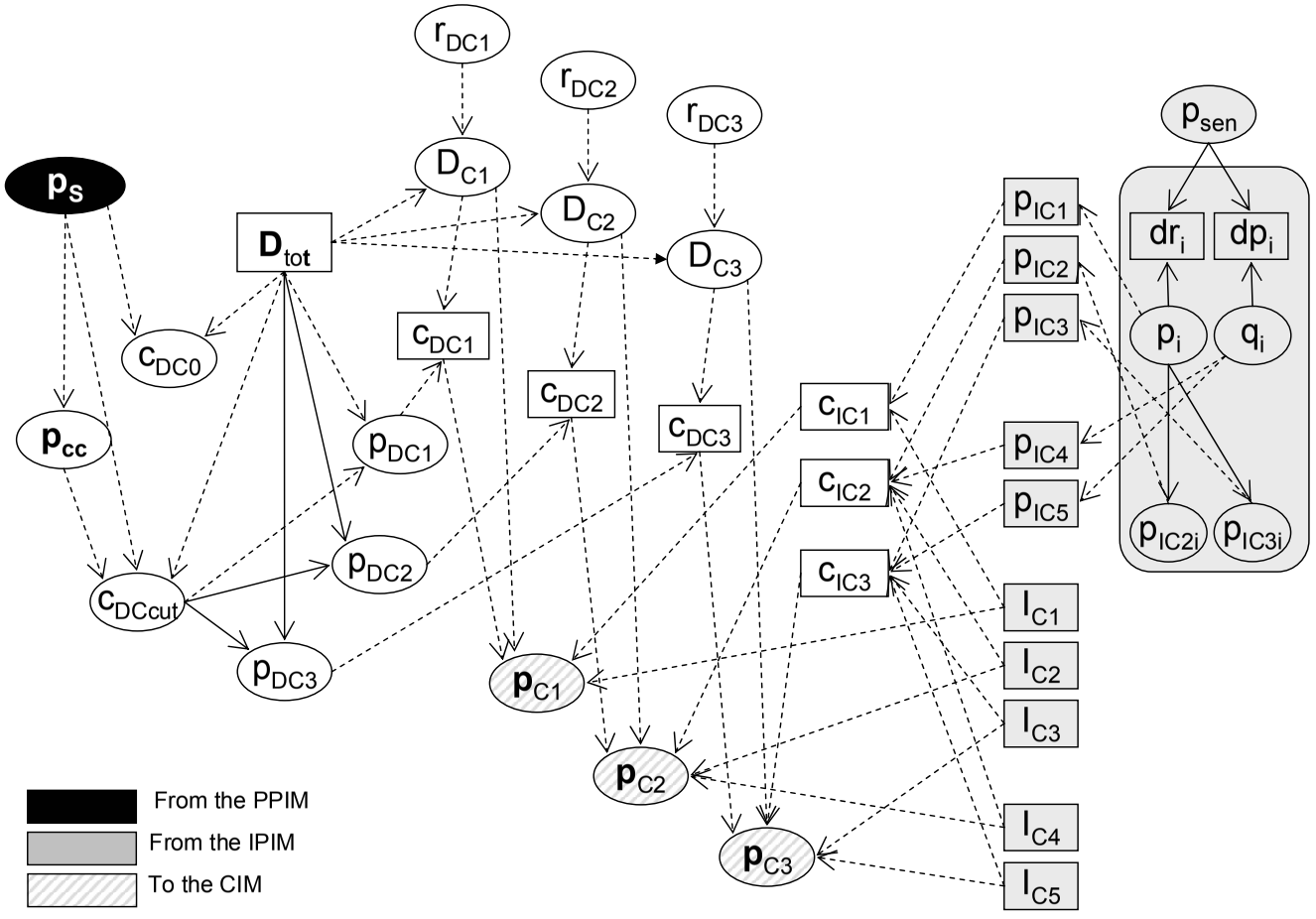

Figure 16. *Graphical description of the Secondary Production Simulation Model (SPSM) that combines the Primary Production Inference model (PPIM) and Import Prevalence Inference Model (IPIM) in the Consumption Inference Model (CIM).*

Explanations to the notations in Figure 16:

c_{DC0}	Amount of contaminated domestic, approved beef before cross-contamination
c_{DC1}	Amount of contaminated domestic fresh beef
c_{DC2}	Amount of contaminated domestic products containing beef and processed at under 70 °C
c_{DC3}	Amount of contaminated domestic products containing beef and processed at over 70 °C
c_{DCcut}	Amount of contaminated domestic beef after slaughter and meat cutting
c_{IC1}	Amount of contaminated fresh beef imported for Finnish retail
c_{IC2}	Amount of contaminated imported preparations and products and contaminated imported beef processed at under 70 °C, after process cross contamination
c_{IC3}	Amount of contaminated imported preparations and products and contaminated imported beef processed at over70 °C, after process cross contamination
D_{C1}	Amount of domestic fresh beef consumed, domestic category 1
D_{C2}	Amount of domestic products consumed containing beef and processed at under 70 °C, domestic category 2
D_{C3}	Amount of domestic products consumed containing beef and processed at over 70 °C, domestic category 3
dp_i	Number of positive tests reported from np_i meat product or preparation samples at retail from the i^{th} country
dr_i	Number of positive tests reported from nr_i fresh meat samples at retail from the i^{th} country
D_{tot}	Amount of approved, boneless domestic beef meat consumed in Finland
I_{C1}	Amount of fresh beef imported to be sold as fresh, Import category 1
I_{C2}	Amount of fresh beef imported to be processed at under 70 °C, Import category 2
I_{C3}	Amount of fresh beef imported to be processed at over 70 °C, Import category 3
I_{C4}	Amount of imported beef products containing beef and processed at under 70 °C, Import category 4, boneless

Explanations to the notations in Figure 16 continued

I_{C5}	Amount of imported beef products containing beef and processed at over 70 °C, Import Category 5, boneless
p_{C1}	Contamination prevalence of imported and domestic fresh beef at the retail level
p_{C2}	Contamination prevalence of imported and domestic preparations and products processed at under 70 °C at the retail level
p_{C3}	Contamination prevalence of imported and domestic preparations and products processed at over 70°C at the retail level
p_{cc}	Resulting prevalence, due to cross contamination, in cut meat resulting from those animals not originally infected
p_{DC1}	True salmonella prevalence of domestic fresh beef after meat cutting
p_{DC2}	True salmonella prevalence of domestic category 2, preparations and products containing beef and processed at under 70 °C
p_{DC3}	True salmonella prevalence of domestic category 3, preparations and products containing beef and processed at over 70 °C
p_i	True prevalence in the fresh beef imports from the i^{th} country
p_{IC1}	Contamination prevalence of imported fresh meat for I_{C1} without special guarantees
p_{IC2}	Contamination prevalence of imported fresh meat for I_{C2} without special guarantees
p_{IC2i}	True prevalence of preparations and products containing beef and processed at under 70 °C, made of I_{C2} imported from the i^{th} country without special guarantees
p_{IC3}	Contamination prevalence of imported fresh meat for I_{C3} without special guarantees
p_{IC3i}	True prevalence of preparations and products containing beef and processed at over 70 °C, made of I_{C3} imported from the i^{th} country without special guarantees
p_{IC4}	Contamination prevalence of imported beef preparations and products processed at under 70 °C without special guarantees
p_{IC5}	Prevalence of imported beef preparations and products processed at over 70 °C without special guarantees

Explanations to the notations in Figure 16 continued

p_s	True salmonella prevalence in the slaughter population, also used as prevalence of contaminated domestic beef before cross-contamination in slaughter and cutting
p_{sen}	Sensitivity of testing method
q_i	True salmonella prevalence in the beef product or preparation imports from the i^{th} country
r_{DC1}	Proportion of domestic beef intended for sale as fresh
r_{DC2}	Proportion of domestic beef intended for products processed at under 70 °C
r_{DC3}	Proportion of domestic beef intended for products processed at over 70 °C

IV Consumption Inference Model (CIM)

The CIM has been developed for conversion of the meat and meat products available for consumption into a risk estimate that assesses the risk of a consumer becoming a human salmonella case and quantifying the uncertainty of the risk estimate (Maijala et al. 2005b). In this QMRA the model was used to produce the risk estimate for human salmonella cases due to the beef production chain (III).

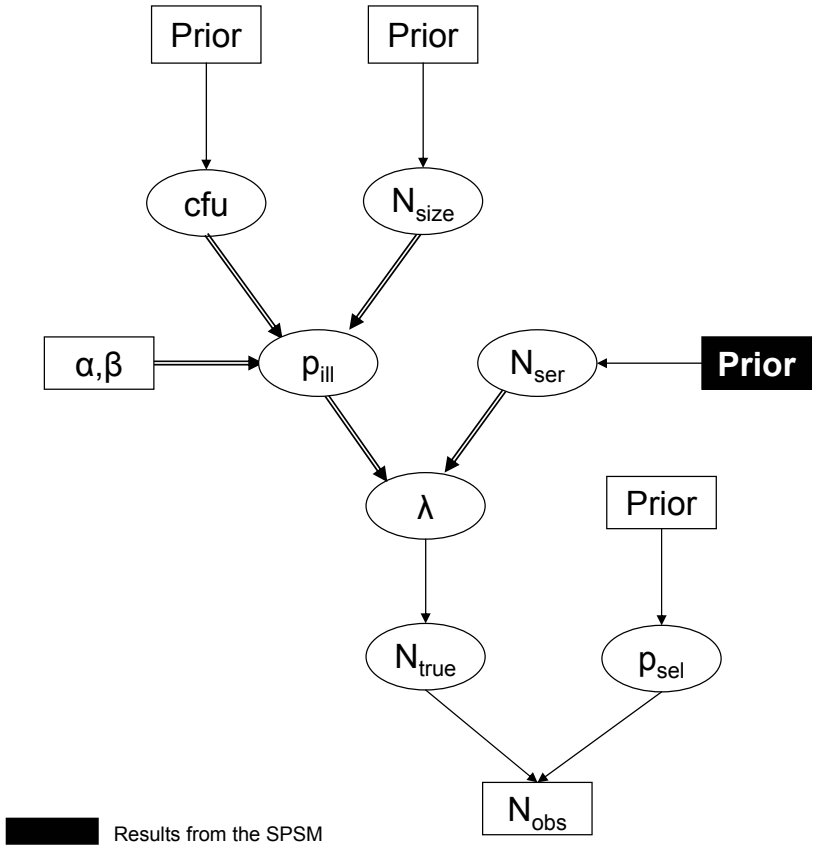

Figure 17. *Graphical description of the Consumption Inference Model (CIM) (Maijala et al. 2005b). Salmonella prevalence in beef and beef-derived food products on the market (pC1, pC2 and pC3 in the Secondary Production Simulation Model on p 119) were converted into a expected number of standard servings and its distribution was used as a prior in the model.*

Explanations to the notations in Figure 17:

α,β	Parameters for the dose-response model
λ	Expected number of human salmonella cases due to beef
cfu	Average CFU/g per an initially contaminated serving at the time of consumption
N_{obs}	Number of reported human cases due to beef during the study year
N_{ser}	Number of servings consumed
N_{true}	True number of human cases due to beef during the study year
p_{ill}	Probability of illness per contaminated serving
p_{sel}	Probability of a case of illness being diagnosed and reported
S_{size}	Average size of a standard serving

ERRATA

The last paragraph on p. 30

In 1995, Finland implemented an in-house control system, called own-checking, in the Health Protection Act (763/1994), Food Act (325/1994) and the Act on Food Hygiene (1195/1996). Own checking (OC), which is a food safety system combining basic GHP measures and elements of HACCP, was further implemented in the new Food Act (23/2003), which includes the regulation concerning food safety except that for feeds.

The last sentence of the first paragraph, p. 37

… as also seen in Finnish foodborne outbreak statistics presented in Chapter 2.2.3.

Table 7, p. 66

Table 7 continued.

Parameter	Value used in QMRA
Number of human cases reported in Finland	3033
Reported number of human cases of domestic origin	656
Number of diverse salmonella serovars common both to human cases and the beef-production chain	7

The first sentence of the first paragraph on p. 69:

According to the QMRA conducted, the true prevalence of salmonella was clearly under the apparent objective of 1% along the food chain from primary production (I) to retail (III) (Table 7).

The last chapter on p. 70

The consumer risk for salmonella in beef was based on a comparison of salmonella serovars (phage type concerning *S.* Typhimurium and *S.* Enteritidis) (Maijala et al. 2005b),

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ISSN 1796-4660, ISBN 978-952-225-013-1 (print)
ISSN 1797-2981, ISBN 978-952-225-014-8 (pdf)
Helsinki University Print, 2008